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PACEMAKERS REVISITED: A SAGA OF BENIGN NEGLECT

HEARING

BEFORE THE

SPECIAL COMMITTEE ON AGING
UNITED STATES SENATE

NINETY-NINTH CONGRESS

FIRST SESSION

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PACEMAKERS REVISITED: A SAGA OF BENIGN NEGLECT

FRIDAY, MAY 10, 1985

U.S. Senate,
Special Committee on Aging,
Washington, DC.

The committee met, pursuant to notice, at 9:30 a.m., in room SD-628, Dirksen Senate Office Building, Hon. John Heinz (chairman) presiding.

Present: Senator Heinz.

Also present: Stephen R. McConnell, staff director; Robin Kropf, chief clerk; Jim Michie, chief investigator; Terri Kay Parker, investigative counsel; David Schulke, investigator; Michael Rodgers, majority professional staff; Sara White, assistant press secretary; Jane Jeter and Bill Benson, minority professional staff; Lucy Savidge, legislative correspondent; Leslie Malone and Kimberly Kasberg, staff assistants; and Dan Tuite, printing assistant.

OPENING STATEMENT BY SENATOR JOHN HEINZ, CHAIRMAN

Chairman Heinz. Good morning. This hearing of the Special Committee on Aging will come to order. We are here today to find out why this Nation's 400,000 pacemaker-dependent older Americans still face serious risks from unnecessary and defective cardiac pacemakers.

It has been over 3 years since this committee's initial investigation, 1 year since the legislative remedy passed Congress, and 4 months since that remedy was to be in operation—and here we are, still asking when will fraud, waste and abuse end.

Last summer, Congress recognized the pressing need to protect the lives of pacemaker-dependent persons from the potentially life-threatening abuses in the pacemaker industry. At that time, we passed a law, which I authored, requiring the Department of Health and Human Services to establish a National Pacemaker Registry. The registry would enable the Department to keep track of defective pacemakers and protect consumers from the impending danger of pacemakers that may short-circuit and go dead. Congress thought the problem so threatening that the law required the registry to be operational by January 1 of this year. That deadline has come and gone, 5 months later, almost, and we are no better off than before.

This committee's investigation, I am sorry to say, reveals a Pandora's box full of crooked manufacturers, greedy doctors and defective products. Congress passed a law last year to close the lid on this box of abuses. But today we will find that the benign neglect of certain Federal agencies to carry out an act of Congress continues to endanger the lives of thousands of pacemaker patients.

Kickbacks are not a thing of the past, either. They are as present today as they were back in 1982. While the Justice Department was successful last year in prosecuting two major pacemaker manufacturers for hundreds of thousands of dollars in kickbacks to doctors, these illegal practices persist in ever more sophisticated schemes.

Defective pacemakers still haunt and endanger older Americans. An ongoing FDA investigation of a major pacemaker company revealed that potentially defective pacemakers have been implanted in the hearts of thousands of Americans. Fortunately, this manufacturer has seen fit to notify physicians and hospitals of their pacemaker problems so that patients are not unduly threatened with hazard or injury.

Unnecessary surgery remains largely unchecked. The committee's investigation has found that an estimated 110,000 older Americans will undergo initial pacemaker surgery this year, and another 30,000 will have their pacemakers replaced. Yet experts estimate that as many as one in three pacemaker implants may still be unnecessary.

Such waste carries great cost in human pain and suffering and the price of an estimated 32,000 unnecessary pacemaker surgeries paid by American taxpayers may run as high as $320 million each year. If the Government collected on warranties from explanted pacemakers, the ones that are replaced alone, at least $25 million could be saved by the Medicare Program each year. Now, $25 million may not sound like a lot of money in Washington. But when we are faced with cuts in essential health care because of the enormous budget deficits, any savings to be had by eliminating waste, abuse or fraud is a far preferable alternative.

Unfortunately, a GAO study I am releasing today shows that sales practices by some manufacturers actually discourage returns of pacemakers which effectively precludes warranty credit. These roadblocks, when added to the inertia in enforcing pacemaker protections, mean that warranties continue to be uncollected, and consumers continue to be vulnerable to inept and unscrupulous pacemaker manufacturers.

Further, it appears that officials in one of the agencies responsible for setting up the registry to correct these ills—namely, the Health Care Financing Administration—have been playing hot potato amongst themselves with the health and safety of pacemaker-dependent Americans.

Apparently, after HCFA told the PRO's, the Peer Review Organizations, to start collecting the warranty data which has to go into the Pacemaker Registry, they turned around and told the PRO's to stop collecting that information because the Food and Drug Administration, and I quote, "now maintains a national registry of pacemakers." But as we know, and as HCFA hopefully knows by now, there is still no pacemaker registry, and specifically, not one at FDA.

The unfortunate consequence of this either incompetence or blatant disregard for the law is that thousands of lives are at risk.

I hope the testimony we will receive today from the representatives of FDA and HCFA and pacemaker patients and experts will shed light on the continuing need for a registry and on the likelihood that it will be put into place in the very near future.

Before hearing from our first witness, I am going to insert into the record the statement of Senator Lawton Chiles, who unfortunately cannot be with us today due to a previous commitment.

[The statement of Senator Chiles follows:]

STATEMENT OF SENATOR LAWTON CHILES

In 1982, after a lengthy investigation, this committee held hearings focusing on sales practices within the pacemaker industry and the costs of pacemaker devices to patients and Medicare.

Those hearings and later legislation prompted several more in-depth reviews of pacemaker practices, and the development of new medical guidelines for implantation and monitoring of pacemaker performance. Still under development are more accurate schedules for Medicare reimbursement.

Today's hearing focuses on one specific aspect of our earlier recommendations: The development of a national pacemaker registry to provide the public, physicians, and patients with accurate information on pacemaker performance.

Pacemaker technology is changing rapidly. New pacers offer the promise of a more comfortable and satisfying life to patients with heart conditions. But there are also problems—and failures. Properly established, a national pacemaker registry can track those failures, provide vital information to physicians responsible for monitoring pacer performance, and protect pacer patients from avoidable stress and, in some cases, life-threatening harm.

A registry was mandated by law to be established over 3 months ago. Virtually nothing has been done to date. I don't see why. It is not a question of cost: A registry could result in considerable savings to the Government through Medicare recoveries under failed pacer warranties.

Most importantly, if Medicare is to continue paying for needed pacers for thousands of Medicare beneficiaries we clearly need to have a better way to monitor the safety and effectiveness of these devices.

Chairman HEINZ. Our first panel consists of Dr. Carolyne Davis of the Health Care Financing Administration and Dr. Frank Young, Commissioner of the Food and Drug Administration.

Dr. Davis, I know that you have to leave here by 10:15, and we will accommodate you. I will therefore ask both you and Dr. Young to be as concise as possible in your opening statements, so that there is adequate time for questions.

I know that—I want everyone to know that—you are the two individuals who head the agencies which are directly responsible for the implementation of the National Pacemaker Registry. I do appreciate your appearance here to respond to our inquiries on the status of that registry.

Dr. Young, I want to also take this opportunity to compliment you and your investigators for their thorough and complete inspections of a pacemaker company. Two of those investigators, as you know, will testify later in this hearing on their findings.

I will now ask both of you, Dr. Davis and Commissioner Young, to rise so I can administer the oath. Would you please rise and raise your right hand?

Do you swear to tell the truth, the whole truth and nothing but the truth, so help you, God?

Dr. DAVIS. I do.

Dr. YOUNG. I do.

Chairman HEINZ. Thank you very much. Let the record show that the witnesses responded in the affirmative.

Dr. Davis, please proceed.

STATEMENT OF CAROLYNE K. DAVIS, PH.D., WASHINGTON, DC, ADMINISTRATOR, HEALTH CARE FINANCING ADMINISTRATION

Dr. DAVIS. Thank you, Mr. Chairman.

I would like to introduce Dr. Henry Desmarais, who is the Director of our Bureau of Eligibility, Reimbursement and Coverage, on my left, who accompanies me today.

I just want to highlight briefly the testimony itself, which has been submitted.

Briefly, as you know, the Medicare Program covers the pacemaker services under both the Hospital Insurance Program, or part A, as well as part B services, and the part B services cover the physician services that are related to the implant surgery, whereas part A covers the services that the beneficiary needs while in the hospital.

We estimate that Medicare is paying for approximately 100,000 permanent pacemakers, according to our 1982 estimate.

Chairman HEINZ. Did you say 100,000 permanent pacemakers?

Dr. DAVIS. Yes.

Chairman HEINZ. What is the difference between a permanent pacemaker and an impermanent one, just so I understand?

Dr. DAVIS. A less-than-permanent pacemaker is one that is put in for a transient problem.

Chairman HEINZ. Just for a brief period or a few weeks?

Dr. DAVIS. Yes.

Chairman HEINZ. All right. Thank you.

Dr. DAVIS. Since October 1983, medical review entities, such as our peer review organizations, have been reviewing 100 percent of permanent cardiac implants and reimplants for medical necessity and appropriateness. To date, we have found that there is approximately a 2-percent decrease in 1984 as compared to prior years, and we believe that probably this is due to the sentinel effect of the peer review organizations.

We have also found that there appears to be an increase in the pacemaker populations that are sicker and have more significnat symptoms. We believe that we can attribute that to the fact that the guidelines that have been issued in relation to the appropriateness of implantation are indeed being followed.

In July 1984, the Deficit Reduction Act [DEFRA] was signed into law, and that included several provisions that dealt specifically with pacemakers. I want to just highlight our progress in implementing them.

First, DEFRA required that we revise the guidelines on the frequency of transtelephonic monitoring. In October 1984, we issued those guidelines, and that did reduce the maximum frequency for the physicians' monitoring the pacemaker transtelephonically and visits by approximately 45 percent. Our guidelines defined the minimum amount of service that was necessary in order to claim reimbursement as a pacemaker monitoring service. Separate guidelines were established for monitoring the single and the dual-chambered pacemaker, rather than having an average for the two, and separate requirements were established for pacemakers that have a proven record of superior performance.

The Deficit Reduction Act also required studies of the appropriateness of part A and part B payments that were associated with the pacemakers. The Prospective Payment Assessment Commission, or PROPAC, has completed its study of the appropriateness of part A payments, and in a recent report that it issued, concluded that the payment under the DRG is appropriate, on the average.

We in HCFA are now in the process of conducting a study of the appropriateness of the Medicare part B reimbursement for cardiac pacemaker services. This study will look at changes in the time, the difficulty and the cost of implantation and replacement of the pacemakers.

Since we did not have the data in-house to analyze the physician costs or time, it was necessary for us to undertake an on-site survey. We expect the results of that study to be available this fall. When it is completed, we will be able to compare our costs in 1984 with costs when the program started, and to report on the appropriateness of the payment amount.

The third requirement was the establishment of a registry of all cardiac pacemaker devices and leads for which payment is made under Medicare. DEFRA stipulated that the Food and Drug Administration would operate the registry, and since the enactment of DEFRA, we have been working closely with the FDA in order to establish the required pacemaker registry.

We have also been developing a draft regulation that is scheduled for publication later this year. Our plans would require that hospitals report the specified pacemaker information to the intermediaries as a condition for Medicare payment. This data would then be transmitted to the FDA. The FDA would maintain the national registry, analyze the data that is submitted by the manufacturers, and inform HCFA of cases where payments may be denied when the devices are not returned when requested, or when the test results are not reported as is required.

I would like to point out that there is some limitation in terms of the potential effectiveness of the registry. Manufacturers are not required to offer warranties on pacemaker devices, and the terms of the warranties when available do vary widely and are sometimes modified during the life of the device—in other words, they are sometimes prorated.

Most of the warranties will only allow for replacement by the manufacturer of a pacemaker of the same type. Frequently, we find that hospitals and physicians may choose to switch to another brand or model. Warranties also vary as to the amount of credit that they do give, prorated as they might be, and sometimes the related medical costs of hospitalization or the surgery are not covered.

It is difficult to determine the amount available under the warranties. Prior to implementation of prospective payment, hospital recoveries on warranties were expected to be included on the Medicare cost report and to be deducted from the hospital's reimbursement. Under the prospective payment system, we have assumed that to the extent that the hospitals did collect on those warranties, it is reflected in the base, and any collections now would be retained by the hospitals.

We did require our peer review organizations to collect information on warranties as a part of their effort to review pacemaker necessity. But we found that the PRO's were not uniformly successful in obtaining warranty information. We deleted the PRO warranty requirement in March 1985. Effective April 1, the warranty information will be collected by the fiscal intermediaries.

So, in summary, Mr. Chairman, we believe that we are well along in fulfilling the DEFRA pacemaker requirements. There are some complicating factors, and I will be happy to highlight those in answering any questions that you may have.

Chairman HEINZ. Dr. Davis, thank you.

Dr. Davis, normally, I would ask Dr. Young to testify, but so that we have plenty of time for you, let me proceed in a sense out of order to ask you some questions on your testimony.

First, by the way, let me compliment you on the job you did on transtelephonic monitoring. I think that was a very significant area of abuse. You will recollect that in 1982, our investigators had to go undercover. They had some extraordinary television taped footage of salesmen coming in and explaining to a doctor how, by overmonitoring patients, they could make an extra $150,000 a year with a receptionist who just stayed an hour or two after 5 o'clock, and used the telephonic monitoring system to make $150,000 or $200,000, or as one of the salesmen said, "The reason you ought to use our pacemaker is that you can make $150,000 extra, and all it costs is stamps," mailing in the receipts or the claims on Medicare for monitoring.

You have done an excellent job, I think, in cracking down on that. I wish that we were that successful in everything we try and do, both you and I together.

Let me also say that I think you understand perhaps better than anyone the major effort that both Congress and the administration have been making to make Medicare a prudent buyer of health services, and any prudent buyer of a complex device costing $4,000 or $5,000—which is what a pacemaker costs—with the kind of track record of recalls—we are up around 22,000 recalls annually the last couple of years—would shop for a good warranty on that device and ask to redeem it.

Now, I want to be certain I understand your testimony on that point. Aside from suing the pacemaker manufacturer for insurance payments, are you saying that HCFA has no authority under present law to recover moneys owed to the Medicare Program for pacemakers that fail due to defects and are explanted during the term of an applicable warranty? Are you suggesting you do not have authority there?

Dr. DAVIS. I think our authority is somewhat murky in relationship to processing the warranty itself. However, if it is a question of liability, and the individual company has a liability insurance policy, we believe that that is covered under Medicare as the secondary payor. So we do have that authority, and we are recommending that we pursue the liability aspect rather vigorously.

But there is some question in relationship to our authority to actually collect on the warranty itself.

Chairman HEINZ. Do you see any reason why we should not give you that authority? I think you would want, assuming that it was cost effective, to go and collect every, single warranty that the Government was owed.

Dr. DAVIS. No, sir; I think our major problem has been that the law, as reviewed by our General Counsel, is a little uncertain in relationship to whether or not we could collect.

Chairman HEINZ. So, you would like us to clarify that. You do not mind having the authority to get money?

Dr. DAVIS. Oh, no.

Chairman HEINZ. Good.

I also know that your agency, the Health Care Financing Administration, has studied the warranty question for a long time. One of the reasons I know is I have a memorandum [1] dated January 27, 1984, by HCFA's Associate Administrator for Operations, which refers to HCFA's study of this issue, going back to the early summer of 1983. And I must say, the memorandum demonstrates an impressive understanding of the problems of collecting warranties. In fact, it really states the same things that you are stating today—that recovering warranty moneys would be possible if the regulations issued were changed, but that it would be difficult to change those regulations effectively because the manufacturers who manufacture the pacemakers control the terms of the warranties, and by changing those warranty terms, may be able to continue to get around the regulations.

Is that a fair characterization of what you are concerned about?

Dr. DAVIS. Well, I think that it is very clear that even if you have the authority there are other problems relative to the multiple manufacturers of these various devices. As I said earlier, in order to be able to collect on the warranty, you would have to have the hospital and the physician agree to use the same model from the same manufacturer the second time around, because that is usually how the warranty is written.

Second, there is also the issue of whether or not the problem is the fault of the lead or the pacemaker itself, or whether it is a fault due to the recipient's tissues, or whether it is the fault of the physician. So you get into some very complex problems, legally, that would have to be sorted out. And that has been part of our concern. We had estimated that the maximum that we could collect, would be in the neighborhood of $17 million, or perhaps even less, depending upon whether or not the warranties were prorated. Again, that is the other issue; failure might occur at some point after the implant, 2, 3, or more years beyond, and many of them do have a prorated warranty.

Chairman HEINZ. Other than rewriting your regulations so that they either do one or both of two things—one, to shop for warranties that are easier to collect under, or two, to write regulations that deal with some of those ambiguities that you just described—is there any other way that you have of getting at this problem?

Clearly, there are a lot of pacemakers that are being reimplanted. Your number is 21,000 a year; our estimate is 30,000 a year.

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[1] See appendix IV, p. 220.

The estimates of what proportion of them are under warranty range, I guess, from a low of maybe 20 percent in our case to a high—and I will tell you where your numbers come from; they come from the PRO's—of 70 percent—if our numbers are correct, we are talking about an $80 million a year bonus that somebody is getting at our expense. If your numbers are correct, it is probably around $17 million—a large difference.

But without arguing too much over whose numbers are right, is there any other method of getting at more than $17 million, that you know of?

Dr. DAVIS. Well, I think that the major problem, as I indicated earlier, has to do with the law itself, not with the regulations. I think we do need more clarity in the law in order to capture more of these dollars. But I am simply making a cautionary statement that even if we have that, there will be lots of litigation that could result in our getting somewhat less than our total.

Chairman HEINZ. Let me return, then, to the subject of the difficulties of obtaining warranties. You have cited that we wrote the warranty provisions of the pacemaker registry section of the Deficit Reduction Act, DEFRA.

The memo I referred to a moment ago, the January 27 memo, indicates that you knew at HCFA that you were having problems back then, a year ago. And I quote from the memorandum: "I am aware of the promises made to Senator Heinz to ease the pressure for passage of his pacemaker legislation. Nonetheless, I believe it is important to note that some of the other difficulties"—and we have just gotten into some of those other difficulties—involved in obtaining warranty recoupment, besides revision of the prospective payment regulation."

What HCFA seems to be saying here is that at least a year or so ago, you knew that there were real problems doing this, but you did not come and tell anybody up here, most specifically, the author of the legislation—me. Why didn't you come and tell us that you had problems then? Why do we have to wait a year to find out that there are problems?

Dr. DAVIS. Well, no, sir. I think we had pointed out last year, when we were discussing this, or 2 years ago, that we believed that the prospective payment system itself does give back to hospitals the incentive to collect on the warranty. Since the prospective payment itself includes the cost of the pacemaker, hospitals have the incentive now to go after warranties, and we can take advantage of that as we recalibrate the DRG's.

Chairman HEINZ. And yet, you are saying that you would like a clearer law, and you would like more authority. What is different today versus a year ago? Are you wiser, or am I misinterpreting what you are saying?

Dr. DAVIS. No. I think there are occasionally times when we would believe that it would be appropriate for us to try to go after those dollars, and we think that the law is not clear at this point in time. That is, it allows the hospital to go after warranties, but we do not think that under the prospective payment legislation we have the authority to go after them.

Chairman HEINZ. Do you have any doubts about whether or not it would be cost effective for HCFA to go after the $17-plus million in warranties that you have indicated?

Dr. DAVIS. Well, as I indicated earlier, that does depend somewhat upon whether they might be prorated. They might go into litigation—frequently, if you go after a warranty, I think that might happen, particularly if there was a large volume. And to the degree that you would then have to offset your court costs, it might well be that we end up without a large savings to the program.

Chairman HEINZ. Well, if you were in the right, wouldn't defendant pay the court costs?

Dr. DAVIS. Assuming that we won—but I long ago realized that not always when we are in the right do we win.

Chairman HEINZ. I assume you would always be in the right.

Dr. DAVIS. We would like to think so, yes.

Chairman HEINZ. But I gather that if we gave you the additional clarification and the additional authority, it would be even easier for you; is that right?

Dr. DAVIS. Yes. What I would be cautious of is that we ought not to assume that the dollar volume, whatever it ends up from what we think it is at this moment, would actually be the amount that we could recoup.

Chairman HEINZ. But you are not contending that even under current law, you are not contending that it is not cost-effective right now for you to go after those warranties?

Dr. DAVIS. If you are talking specifically of the warranty issue and not the liability issue, because I see them as two separate issues.

Chairman HEINZ. Yes.

Dr. DAVIS. I think here again, given the fact that our estimates were in the neighborhood of the $17 million, that there would potentially be some cost savings. But I would caution that it is probably far less than what we had initially anticipated, because of the prorating and litigation as to whose fault it really is.

Chairman HEINZ. But your number of $17 million, as I understand it—and correct me if I am wrong—is what HCFA would get if they went out to——

Dr. DAVIS. That is what we had estimated our maximum that we could collect would be.

Chairman HEINZ. All right.

Now, we are paying PRO's to review 100 percent of pacemaker surgeries, and on the second or third page of your statement, you make the comment that the PRO's have reviewed 100 percent of all permanent cardiac implants and reimplants for medical necessity and appropriateness. I would like to look at what we have really bought, because I think that information may turn out to be inaccurate. I do think that PRO's have gathered a great deal of valuable information on warranties. You did hint in your statement there were some problems. I think you said that the PRO's were not uniformly successful gathering the warranty information. I would say that that is, from what I know, a great understatement. Reviewing their monthly reports, it becomes clear that what they were successful—or, should I say, uniformly unsuccessful—in gathering the warranty information. According to the 336 monthly reports filed by PRO's with your agency, HCFA, up through January—and that, I believe, is the total number of monthly reports filed by PRO's—they only reviewed pacemaker surgeries not at 100 percent, but at an annual rate of only 35 percent, one-third of what you and I would have hoped to have been the case, and that 35 percent is based on their very best month. So that is a high figure, if anything. And those reports also indicate that the PRO's gathered appropriate warranty information in only about one-quarter of those 35 percent of the cases which they actually reviewed.

My question is, I suppose, what has HCFA done about the poor performance of the PRO's in this area. Maybe you are not aware of it, because in your statement you were saying they are reviewing 100 percent. Our information, going through the actual reports, report by report, 336 of them, is that they are doing one-third of that.

Dr. **Davis**. Well, let me clarify a couple of points on that, if I can, Mr. Chairman. It is still my belief that they are doing 100 percent review. That is what we have told them to do. When our people in the regional offices go onsite to check, we find that is what they are doing. I think the problem is a perception problem because of the reporting mechanism. Our reports come in on only those hospitals that are under prospective payment. In fiscal year 1984, roughly about 42 percent of all our bills were processed under prospective payment. Because the PRO reviews were from a prospective payment report, our PRO reports show only that portion of pacemaker cases. So, if you take the 35,000 that were performed and assume that that is the 42 percent performed in PPS hospitals, we would come out with approximately 78,000, I believe, pacemaker reviews for all hospitals.

In addition, there is a lag time, and I think it is important to recognize that in relation to the total reviewing mechanisms. They must wait for what we call the PATBILL to be sent to them, and then for the medical records component. So there is usually about a 3- to 6-month lag time in their reporting mechanism. In relationship to our being able to check on the volume that is actually being paid, we rely upon the PATBILL, which comes to us generally about 2½ months after the actual implantation.

So we think that we do have evidence that they are reviewing 100 percent. Second, with maybe one exception——

Chairman **Heinz**. On that point, let me suggest this. We have had very good cooperation from your agency, and because of that cooperation, we sent a member of my staff down to your agency, and we physically, staff physically went through, the 336 monthly reports, the totality of the PRO reports, that you have received.

I think if you either sit down with our staff, or you send a member of—how many people work at HCFA?

Dr. **Davis**. About 4,000.

Chairman **Heinz**. About 4,000. If 1 of those 4,000 people would take the time just to go through those 336 reports, it would probably take them several hours, maybe a day, and I think you would find, contrary to your impression, that rather than 100 percent of the implantations being reviewed, less than one-third, or no more than one-third, are being reviewed. And that is a matter of fact, and I think you can set that in order. I would like you to please double-check your numbers and give us a note, a letter, an amendment to the testimony, so that that is clear.

Dr. DAVIS. I would be happy to do that.

Chairman HEINZ. Either our investigators cannot count—and I know we have educational problems in this country, but I do not think they are that bad—or the information that is down there is not filtering up.

I know there are things I do not know, too, that I ought to know, so maybe you are a victim of those kinds of circumstances.

Dr. DAVIS. I would be happy to have our groups sit down together and go over that data.[2]

The monthly PRO reports do not reflect their total review of pacemaker insertions. These reports only include reviews of pacemaker procedures performed in prospective payment [PPS] hospitals, or approximately 42 percent of all pacemaker insertions.

During 1984, we estimate that approximately 83,000 pacemakers were inserted or reinserted in Medicare beneficiaries. Of this total, 35,000 pacemakers were inserted in PPS hospitals and were reported on the PRO monthly reports. An additional number of pacemaker procedures were performed in PPS hospitals but were not included in the 1984 reports because inaccurate data from processed bills delayed the PRO review. We estimate that an additional 43,000 pacemaker insertions were performed in non-PPS hospitals and were reviewed by PRO's. These non-PPS procedures were not included in the monthly reporting system. We believe this accounts for very close to 100 percent of our pacemaker insertions.

Chairman HEINZ. I apologize. I interrupted you in the midst of a summation.

Dr. DAVIS. If I could just make one other point there, and that was in relation to the fact that you indicated that the Peer Review Organizations are not doing a good job of collecting on the warranty information. We would agree with that. That is exactly why we stopped having the Peer Review Organization responsible for that. They are a medical review entity, and as such they simply were not equipped to get that kind of data back from the hospitals. It was excessively time consuming, burdensome; they were not getting it. And so it seemed more appropriate, since they are a medical review agent, to return that function to the fiscal intermediary that is accustomed to dealing with reimbursement recoupment issues.

So, as of April 1, the fiscal intermediaries are the ones who are directed to collect that data.

Chairman HEINZ. Are the fiscal intermediaries going to do that for free, or are you going to have to pay them?

Dr. DAVIS. Well, it will be encompassed as a part of their overall budget activity. We estimate that it will cost some money for them to do that, but we include that within the overall budget that is negotiated with them.

Chairman HEINZ. It is going to cost you, what, at least $1 million?

Dr. DAVIS. About $1.3 million.

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[2] See appendix IV, p. 508.

Chairman HEINZ. In the Request for Proposal that we sent to PRO's, didn't we spell out very clearly that we expected that as a condition of participation or fulfillment of contract, that they were required, in order to meet the terms of a contract between the Government and themselves, that they would, No. 1, review 100 percent of pacemaker implantations and No. 2, collect that warranty information? Is that not a contractual requirement which we, the Government, are paying for?

Dr. DAVIS. It is very clear that in our contracts we did indicate that we expected 100 percent review. As to whether or not within the contract we had language as to the specific warranty part, I would have to go and check and submit that for the record.[3] But I am comfortable with the fact that we are monitoring them on the 100 percent compliance part.

Chairman HEINZ. Well, my concern is that we are going to pay twice for the information we only need once; that we have signed these contracts—and I do not want to spend a lot of time on that point, but you may want to see if there is some way we do not have to pay for the same information twice.

I do have here, thanks to my efficient staff, on page 65 of a document from HCFA Request for Proposal.[4] It does at this point say, "For every pacemaker reimplantation, obtain warranty information necessary to identify pacemaker costs reimbursable to Medicare." And then there is a double asterisk, and it says, "The contractor shall perform these activities according to the specifications in attachment 4 to the RFP." I do not happen to have attachment 4 handy, but I would imagine that when anything is pointed out with that kind of specificity, that it is probably pretty clearly covered.

Dr. DAVIS. Yes.

Chairman HEINZ. Well, let me move on a little bit, here. There is a HCFA Interim Manual Instruction[5] dated March 1985, which says, and I quote: "HCFA eliminated the requirement to collect pacemaker warranty information by the PRO's, as the Food and Drug Administration now maintains a national registry on pacemakers." That is from 2 months ago, March.

As Dr. Young will testify to in a minute, there is not yet at FDA any national pacemaker registry. It was supposed to be in effect the first of this year. We all miss deadlines now and again. But I am concerned that the important decision to stop collecting information on pacemakers through the PRO's, without making sure that there was some other method of collecting that information—you yourself have indicated that the fiscal intermediaries are going to be at some future point collecting that information, once you work out the details, get the money, and so forth—that the decision to stop the PRO's doing it appears to have been reached based on erroneous information—namely, the rationale described in the memorandum, that FDA was already keeping the registry.

How is it possible that your folks did not know that there was no registry?

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[3] See appendix III, pp. 161-193.
[4] See appendix III, p. 163.
[5] See appendix IV, p. 465.

Dr. DAVIS. I think, if I may go back, that that point must be clarified, because I think you may have misperceived something I said earlier.

What I was trying to indicate was that we had made the decision to stop having the PRO's do the collection of the data, but the fiscal intermediaries are already doing that. As of April 1, 1985, they are now collecting that data, so that there is not a gap.

Chairman HEINZ. All right. What about the perception, though, that there already is a national registry?

Dr. DAVIS. I think the intent, probably—and I have not seen that memo recently—was simply to indicate that the FDA registry would be the sole source which we would be utilizing for all of our pacemaker activities, and therefore it is no longer a component that we would have done by the Peer Review Organizations.

I think the most important part is that we do have a mechanism in place to collect that data. The Peer Review Organizations were not successful—and I think it was mostly not their fault—they simply are not equipped to collect the kind of data that is absolutely necessary to have onhand. When you think about tracking a warranty issue, you realize that we have to have data as it relates to the manufacturer, the model number, the serial number, the recipient's health insurance number, the date that it was implanted or reimplanted, the provider numbers, the physicians' I.D. numbers. There are so many numbers that the ability of the Peer Review Organization to even possibly get all those correct is very limited. We think it needs to be within the fiscal intermediary, where there is a different edit system that can actually guarantee our success in this, because our success in collection will only be as good as our data base.

Chairman HEINZ. Well, when you say it is not possible for the PRO's to get that kind of information, if they cannot get it, I guess there are two things that trouble me. One thing that troubles me is that they agreed to get it. That is what all this fine print is about. And either the ones we signed contracts with were incompetent, or they were unfamiliar, or they just wanted to take us to the cleaners, or they could not read—one of those three explanations seem to cover all of the bases.

I have some trouble with the notion that this information is all too complicated to get. It is there, and in this day and age, when computers really keep track of everything, it troubles me that we are saying that that information is just not available.

Dr. DAVIS. Well, let me clarify a couple of points here. First of all, I would want to check the actual contract itself. What you were reading from, I believe, was the request for proposal, and we sometimes modify the proposal to the actual contract. So I will submit for the record exactly what the language is in the specific contracts as it relates to that:

The original PRO contracts (Article III.B.1.a. (iii) and (iv)) included two requirements related to pacemakers:

"Review every permanent cardiac pacemaker implantation or reimplantation procedure and deny payment for all that are unnecessary."; and,

"For every pacemaker reimplantation, obtain warranty information necessary to identify pacemaker costs reimbursable to Medicare."

We decided subsequently that this activity was not an efficient use of the PROs. Our March 1985 Interim PRO Manual Instruction rescinded the requirement for

PROs to collect pacemaker warranty information, but at the same time, added new PRO review requirements in other areas, such as review of DRG claim adjustments requested by hospitals. In effect, we have achieved an offset of cost and labor under the PRO contracts.

Chairman HEINZ. All right.

Dr. DAVIS. Second, the medical review is a review of the medical necessity of admission. The PRO's get a chart that contains that type of information sent to them from the hospital that does not necessarily contain the kinds of data relating to the serial numbers, the model numbers and things of that nature. That is, I think, where the problem lies. We were requesting data that was in addition to the medical data that would normally be submitted. Because it was not forthcoming, we felt that it was better for us to obtain that information through an edit in the fiscal intermediaries' claims systems. The intermediaries relate back to the hospitals and can send the letter directly to request additional information, I think, far better than a medical review entity, which is simply not equipped to do that—they are not into reimbursement and recoupment issues, whereas the fiscal intermediaries are.

And as a final note, I would just simply say that when we allow a Peer Review Organization to not do a particular task, we substitute another one, so we are not paying double money. We would be asking them to do something in lieu of that.

Chairman HEINZ. I guess my last question is, I understand that there has been some discouragement and some criticism within the staff at FDA that the cooperation of HCFA with FDA, in setting up the registry, has been something less than terrific.

Now, I do not know whether that is justified or not, but I do know that there is a memorandum [6] from staff at FDA—and I quote—that says—and I will put the entire document, as soon as I can get the sticker off of it, into the record—it says at the beginning at the paragraph,

> The major stumbling block and cause for the delays—in setting up a pacemaker registry—has been a reluctance by HCFA to commit to any role which, given the thrust and intent of the legislation, is critical.

I think what they are saying, Dr. Davis, is that there was a somewhat uncoordinated response at HCFA to the legislative mandate, and apparently, no single person was ever put in charge and held accountable for the effort.

Is there someone besides yourself—and I am not saying it should be yourself, because I know the enormous responsibilities that HCFA has—but is there someone other than yourself who has been charged with the accountability of making your agency's role helpful and accountable for cooperating with FDA in the establishment of the registry?

Dr. DAVIS. Yes, there is. That would come through our Bureau of Eligibility, Reimbursement and Coverage, primarily the Coverage Division.

I would like to say, however, that I would differ very significantly with whomever wrote that memorandum, that we have not been cooperative. We could submit to you for the record a list of times and meetings that have taken place going back to last August when we first started meeting, and the record would show that we have met almost monthly on this issue, with discussions on some of the details.

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[6] See appendix VI, p. 444.

As I indicated, getting the registry in place is very complex. Getting the regulations to reflect what you need to collect the data for the registry is also complex. There have been just an enormous series of meetings that have been taking place, and to the best of my knowledge, I think Dr. Young would indicate, as I do, that there has been mutual cooperation.

Chairman HEINZ. Is the nub of the problem, though, that you are just not getting good information from the PRO's?

Dr. DAVIS. No, sir. I think that in relationship to the regulation itself, there has been a great deal of discussion going on relating to the complexities of the data that we need to collect in order to have the data base for the registry itself; the issues as they relate to the legalities of the issues involved. We need to always, as we write these, get General Counsel involved in what our statutory authorities are. Those need to be ironed out. And I think there were some issues that the FDA itself had, related to how you would structure that. We need all of that in the decisionmaking process before we can write the regulations with great clarity.

Chairman HEINZ. I gather Dr. Young has a comment he would like to make.

Dr. YOUNG. Senator, I would be happy to submit for the record the chronology that we have put together of those activities. They did begin on August 14, 1984, and we have had 16 meetings over that period of time. The difficulties that are present are more related to the types of information, which I would be happy to also submit for the record, as I have asked those to be summarized as well.

Chairman HEINZ. Very well.

Dr. YOUNG. It is a very complex task to get a registry together for 150,000 important cases per year. But I will submit this for the record.

[Subsequent to the hearing, the following was submitted for the record:]

CHRONOLOGY OF MEETINGS BETWEEN HCFA AND FDA

August 14, 1984: Letter from FDA to HCFA scheduling first meeting between the two agencies to discuss registry.

August 29, 1984: First meeting between FDA and HCFA. Purpose was to review statutory requirements and share initial ideas on implementation strategy.

September 9, 1984: Letter from FDA to HCFA containing a list of FDA's data requirements.

September 26, 1984: Letter from HCFA to FDA containing HCFA's list of data requirements.

November 16, 1984: Second meeting between FDA and HCFA. Purpose was to discuss how HCFA's intermediary network could be used to collect registry data.

January 23, 1985: Letter from HCFA to FDA stating HCFA's understanding regarding FDA's and HCFA's respective areas of responsibility.

January 24, 1985: Third meeting between FDA and HCFA. Purpose was to discuss the development of regulations.

January 25, 1985: Letter from HCFA to FDA transmitting draft form to be used by intermediaries to collect registry data from hospitals.

February 22, 1985: Letter from FDA to HCFA suggesting establishment of a formal FDA/HCFA working group.

March 1985: HCFA phone response to FDA's memo of February 22 agreeing to establishment of formal group and providing names of HCFA representatives.

March 29, 1985: Memo to HCFA/FDA working group members from group chairperson (FDA) announcing first meeting of working group.

April 3, 1985: Fourth meeting between FDA and HCFA. Purpose was to discuss schedule for the development of regulations.

April 5, 1985: First meeting of formal FDA/HCFA working group. Each representative was asked to submit his or her group's response to a list of unresolved issues. HCFA provided FDA with preliminary specifications for regulations.

May 2, 1985: FDA received first draft of the regulations from HCFA.

May 8, 1985: FDA received second draft of regulations from HCFA.

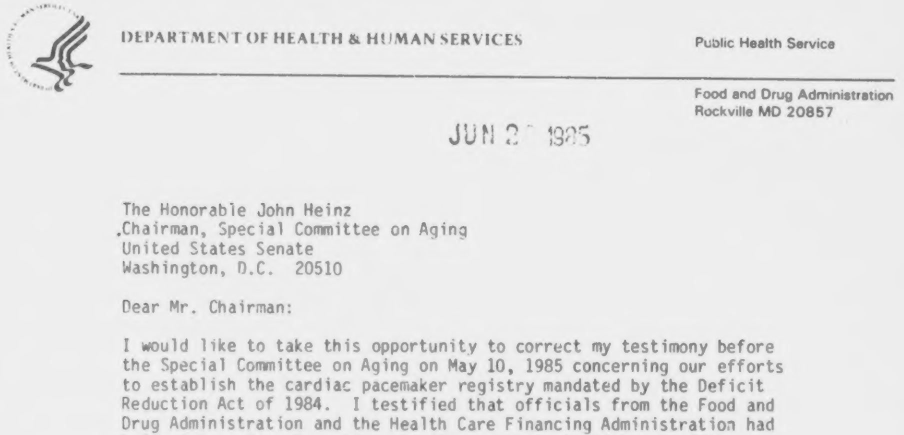
May 8, 1985: Letter from HCFA of FDA requesting comments on proposed data collection form and instructions to intermediaries on data collection.

May 9, 1985: Submission of HCFA/FDA working group of HCFA assignments on various issues from 4/5 meeting.

May 30, 1985: Meeting between FDA and HCFA to discuss the drafting of a Memorandum of Understanding between the two agencies.

May 31, 1985: FDA responded to HCFA's May 8 letter providing formal comments on both the elements and May 8 draft of regulations.

Note: In addition to the above items, there have been numerous phone calls (approximately one per week) between FDA and HCFA staff from August 1984 to the present.



DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
Rockville MD 20857

JUN 2[illegible] 1985

The Honorable John Heinz
Chairman, Special Committee on Aging
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

I would like to take this opportunity to correct my testimony before the Special Committee on Aging on May 10, 1985 concerning our efforts to establish the cardiac pacemaker registry mandated by the Deficit Reduction Act of 1984. I testified that officials from the Food and Drug Administration and the Health Care Financing Administration had held sixteen formal meetings to discuss the establishment of the registry.

As the chronology I am submitting for the record indicates, significant interactions occurred between the two agencies on sixteen dates prior to the hearing, five of which took the form of formal meetings. There were, of course, numerous and regular phone conversations that are not specifically listed in the chronology. I apologize for the error and appreciate the opportunity to offer this correction.

Sincerely yours,

Frank E. Young, M.D., Ph.D.
Commissioner of Food and Drugs

Chairman HEINZ. All right.

Dr. Davis, I know you have some other commitments this morning. I want to thank you for being here. Is there anything else you would like to comment on or say? I think you have covered the waterfront pretty thoroughly, as always.

Dr. DAVIS. Yes, I think we have. Thank you, Mr. Chairman.

Chairman HEINZ. Thank you very much.

We appreciate your coming.

[The prepared statement of Dr. Davis follows:]

PREPARED STATEMENT OF CAROLYNE K. DAVIS, PH.D.

I am pleased to be here today to discuss the cardiac pacemaker provisions under the Deficit Reduction Act (DEFRA) and the Health Care Financing Administration's (HCFA) progress in meeting them. Accompanying me today is Dr. Henry Desmarais, Director of the Bureau of Eligibility, Reimbursement and Coverage.

BACKGROUND

The first pacemaker was developed in 1932 and it was a large device with an external generator and motor. By 1958, with the availability of the transistor battery, pacemakers could be implanted in the body; by 1970, pacemakers were much smaller and lighter, and the pacing frequency could be controlled to the patient's needs. In recent years more sophisticated devices have been developed that pace both chambers of the heart, and that use lithium-powered batteries, thus extending the life of a pacemaker. These cardiac pacemakers have improved the quality of life, and in many cases the life expectancy, of over 500,000 heart disease patients.

Medicare covers pacemaker services under the hospital insurance program (part A) and medical insurance program (part B). The part A program pays for services needed by the beneficiary in the hospital related to implanting a pacemaker, including the device, chiefly through four diagnosis related groups (DRG's) under our hospital prospective payment system.

Part B covers physician services related to the implant surgery, followup care, and monitoring and clinic visits. These services are reimbursed at 80 percent of the reasonable charge.

Medicare pays for approximately 100,000 permanent pacemaker implants (or reimplants) per year. Since 1981, the average price of a pacemaker and lead has increased 32 percent due to changes in both the price and mix of pacemakers implanted in Medicare beneficiaries. In addition, the number of beneficiaries who receive pacemakers has increased with technological advances that increase the number of cardiac conditions where pacemaker implantation is safe and efficacious.

In October 1983, we implemented a prospective payment system for hospitals. We believe the prospective payment system corrects many of the problems found under our cost-reimbursement system related to excessive payment and overutilization. This system provides hospitals with a greater financial incentive to assure that the price they pay for pacemakers and related services is prudent. For example, hospitals now have an incentive to identify when devices are "marked up" unnecessarily and to take advantage of bulk purchase discounts. By prohibiting the shifting of costs covered under part A to part B, the prospective payment system also assures that payment for all pacemaker devices is controlled through our diagnostic related group (DRG) payment.

Since October 1983, medical review entities, such as our peer review organizations (PRO's) have reviewed 100 percent of all permanent cardiac implants and reimplants for medical necessity and appropriateness. To date, we have found that the percentage of implant procedures decreased by about 2 percent in 1984 compared to the prior year. We also found an increase in permanent cardiac pacemakers in patients who are sicker and have more significant symptoms.

Prior to 1938, we did not have specific guidelines to determine which medical conditions should be considered for cardiac pacemaker implantations. Thus, our intermediaries made individual decisions based on whether an implant was "reasonable or necessary" for an individual patient. In March 1983, based on recommendations from the Public Health Service, we issued guidelines that grouped specific medical conditions into three categories according to whether the peacemaker is considered appropriate or not. These guidelines permit our contractors to determine clearly whether a given implant should or should not be covered, serve as the basis of PRO review criteria, and help ensure national consistency in processing claims for these services.

In July 1984, the Deficit Reduction Act (DEFRA) was signed into law, DEFRA included several provisions that deal specifically with pacemakers, I will describe our progress in implementing them.

TRANSTELEPHONIC MONITORING

DEFRA required that we revise the guidelines on the frequency of transtelephonic monitoring. In October 1984, we issued guidelines which reduced the maximum frequencies for physician monitoring of pacemakers by transtelephone and visits by about 45 percent. Our guidelines also define the minimum amount of service necessary to claim reimbursement as a pacemaker monitoring service; establish separate guidelines for monitoring single-and dual-chamber pacemakers, rather than averaging the two; and establish separate requirements for pacemakers which have a proven record of superior performance. The increased specificity of these guidelines should reduce the incidence of unnecessary monitoring. We are continuing to review additional refinements that may be appropriate, such as the establishment of standards for equipment and training of Laboratory staff.

PACEMAKER STUDIES

The Deficit Reduction Act required studies of the appropriateness of part A and part B payment amounts associated with pacemakers.

The Prospective Payment Assesment Commission (PROPAC) has completed its study of the appropriateness of part a payment. It concludes that the payment under DRG's is appropriate on average, since Medicare payment is very nearly equal to the estimated average costs to the hospital. The study recommended that our DRG's for pacemakers be recalibrated in the same manner as other DRG's, to reflect changes in practice since 1981. The study identified a number of factors that might affect future recommendations for changes in the pacemaker DRG's, such as the increase in use of more sophisticated pacemakers with higher cost per discharge, and the lack of specificity in procedure coding for pacemaker recipients. However, further analysis needs to be conducted before specific recomendations can be made, PROPAC is conducting additional studies to review these issues.

HFCA is now in the process of conducting a study of the appropriateness of Medicare part B reimbursement for cardiac pacemaker services as required in the Deficit Reduction Act. This study will look at changes in the time, difficulty and costs of implantation and replacement of pacemakers. Since we did not have the data inhouse to analyze physician costs or time, it was necessary to undertake an on-site survey. Our teams are now visiting hospitals and carriers to collect data on average time for pacemaker procedures, patient condition, surgical team composition, and part B costs. When this information is analyzed, we will be able to compare our costs in 1984 with costs when the program started and report on the appropriateness of payment amounts. We expect the results of this study to be available this fall and will be making recommendations as necessary.

PACEMAKER REGISTRY

A third requirement in the Deficit Reduction Act is the establishment of a registry of all cardiac pacemaker devices and leads for which payment was made under Medicare. DEFRA stipulates that the Food and Drug Administration (FDA) operate the registry. The registry is to include information on the manufacturer, the device, the recipient, the physician or provider, and warranties. The registry is intended to trace the performance of pacemakers and leads; to assist in the determination of when Medicare payments may be proper; and to determine when inspection by the manufacturer may be necessary. The Secretary may deny Medicare payment if physicians and providers fail to comply with these reporting requirements. In addition, the Secretary may require that any devices or leads removed from a Medicare recipient be returned to the manufacturer for testing and that the manufacturer report on the test results and warranty coverage to the provider. Medicare payment may also be denied if the manufacturer fails to perform the test and report on the test results.

Since the enactment of DEFRA, we have been working closely with the FDA to establish the required pacemaker registry. We have been developing a draft proposed regulation that is scheduled for publication later this year. Our plans would require hospitals to report specified pacemaker information to intermediaries as a condition of Medicare payment. This data would be transmitted to FDA. FDA would maintain the national registry, analyze the data submitted by manufacturers, and inform HFCA of cases where payment may be denied when devices are not returned when requested or test results are not reported. We are working out the details of a number of operational issues such as a method to deny Medicare payments through intermediaries and carriers and methods to transmit information among the various parties.

However, it should be pointed out that the potential effectiveness of the registry may be limited. Manufacturers are not required to offer warranties on pacemaker devices and related medical costs. Thus, many devices are not covered under a warranty. The terms of warranties when available vary widely, and are sometimes modified during the life of the device. Most warranties only allow for the replacement by the manufacturer of a pacemaker of the same type. Hospitals and physicians may choose to switch to another brand or model. Warranties also vary as to the amount of credit they give. For example, most warranties pro-rate the costs of the device. Related medical costs such as hospitalization or surgery are often not covered, or only covered in part—usually limited to those costs not paid by a third party insuror or by Medicare. Warranties may limit payment only to the beneficiary. In addition, a warranty can only be honored by a company that remains in business, and there has been much turnover in the pacemaker industry.

For these reasons, we believe that actual recoupments under pacemaker warranties are very small. It is difficult to determine the amount available under warranties. Prior to implementation of PPS, hospitals who recovered on warranties were expected to include the amount of such recoveries on the Medicare cost reports to be deducted from reimbursement. There was no incentive for hospitals to collect or report warranties. A 1982 look at 129 patient records regarding pacemaker experience showed a maximum available from defective or warranteed pacemakers might be $17 million nationwide. But this number assumed that warranties would cover the full costs of the device, an assumption we know to be incorrect.

Under PPS, we have assumed that to the extent that hospitals did collect on warranties, it is reflected in the base—any collections now will be retained by the hospitals. They are not, however, required to report such collections discretely. As a result, it is not possible to determine the amount being collected on pacemaker warranties. Based on the limitations of warranties it is not likely to be substantial.

We did require our PRO's to collect information on warranties as part of their effort to review pacemaker necessity. We found that the PRO's were not uniformly successful in obtaining warranty information for a number of reasons—warranties cannot be considered "medical review"; collecting warranty information is generally not part of the medical records reviewed by PRO's and information was usually collected after Medicare payment was made. Since the Deficit Reduction Act mandated a registry through the Food and Drug Administration (FDA), we deleted the PRO warranty report requirement in March 1985. The initiation of warranty data collection by intermediaries as of April 1, 1985, assures that a continuous mechanism for collecting information on pacemaker warranties is in place and can be utilized by the registry once it is operational.

As noted above, warranties do not cover the medical costs, such as hospitalization and surgery, associated with replacement of defective pacemakers. Medicare must pay there costs. Medicare may be able to recoup some of the medical costs from the manufacturer's liability insuror, however, we may have to establish negligence and make a claim through the legal system which is clearly time-consuming.

CONCLUSION

We believe that we are well along toward fulfilling the DEFRA pacemaker requirements. We believe our revised medical necessity and monitoring guidelines will encourage physicians to be more cost conscious, however, we will consider the need for additional part B payment reforms when the results of our study are available later this year. We are also working closely with the FDA to assist in the establishment of the pacemaker registry. Finally, the prospective payment system has reordered priorities and incentives for hospital payment that should correct earlier problems with pacemakers. Preliminary evidence suggests that this is in fact occurring, and we will continue to monitor performance in this area.

Chairman HEINZ. Dr. Young, you were kind enough to permit Administrator Davis to make her opening remarks. It is now your turn.

STATEMENT OF FRANK YOUNG, M.D., WASHINGTON, DC, COMMISSIONER, FOOD AND DRUG ADMINISTRATION

Dr. YOUNG. Thank you very much. In view of the materials that you have already covered, there is really very little information that I can add beyond my prepared statement.

Chairman HEINZ. Please proceed.

Dr. YOUNG. A few points are very important. First, it is necessary to emphasize that FDA has, with the device amendments, the important responsibility of ensuring the health and safety of the American public in regard to devices. This is a responsibility that we take very seriously. We undertake it in a number of ways.

First, FDA regulates the pacemakers and other industry by requiring manufacturers to demonstrate before marketing whether in this case, pacemakers, or in another case, other devices, meet the appropriate standards that make them safe and effective and/or are equivalent to devices produced before the 1976 act.

Second, we inspect the plants, looking for good manufacturing process. You will be hearing some of the reports of our inspectors later on today.

Third, we keep track by three mechanisms of a variety of devices. The first method deals with the device experience notification. This primarily comes in from physicians.

More recently, through the MDR registry, we are collecting information on many devices and we have received, in the very short time since it has been in operation 392 reports relating to pacemakers themselves.

The third is the development of the registry described in the testimony of Dr. Davis based on your own efforts. The most important thing in bringing the registry forward was the establishment of an effective registry that not only would fulfill the requirements of the law, but the spirit of the law. Therefore, we have been working with our group at FDA under the leadership of Mr. John Villforth, who is on my immediate right, and is the Director of the Center for Devices and Radiologic Health, and my counsel, who is Mr. Scarlet, next down on the right, to determine how this registry can be implemented from a scientific standpoint and from a regulatory standpoint.

At the moment, we are looking at the types of data that should be submitted. These include the model number, the serial number, not only of the pacemaker, but of the leads as well; the date of implantation of the leads and the pulse generator, and the date of explant, when that is required. Of the approximately 150,000 pacemakers that will be implanted per year, approximately 20 percent of those receiving the pacemaker are pacemaker-dependent or pacemaker-strongly influenced.

It is also important to note that approximately 3 to 4 percent of pacemaker patients will have the potential for a life-threatening event if the pacemaker fails, and therefore, this type of information is very critical to protect not only in a retrospective, but as you pointed out, in a prospective basis, those individuals that are getting pacemakers.

In addition, we need to design data forms for the new implants, the explants and the explants of pacemaker needs, and we need to be able to put these forms together to require a minimum effort for filling out, and also a maximum possibility, that these forms will be fully complied with.

I have previously had the privilege of directing a medical center with a hospital of 760 beds, and I know the complexity of gathering this type of information and having such information available for a registry.

So, in summary, FDA is working very hard with HCFA; we intend to see the registry put into place as rapidly as we possibly can effect it, and we look forward to this registry providing information that will help us and will complement the other types of reporting activities that we have, so that we can deal with this very difficult question of medical technology devices.

I need not add or remind you that there is a problem as we build more and more artificial parts for mankind. The parts that we were created with have a shelf-life. Regretfully, there is a shelf-life to parts that are transplanted and implanted. It is our job to make sure that that shelf-life is as long as possible, that it is put in with the best possible forward analysis, but we must realize as physicians that it is very difficult to guarantee devices fully.

That concludes my informal remarks. Thank you.

Chairman HEINZ. Well, thank you, Dr. Young, and I will see that your entire statement, as if given in full, is part of the record.

One of the things you said, and Dr. Davis touched on it herself, that really puzzles me is that you say, well, I have been working on this since August 1983—is that right——

Dr. YOUNG. No; 1984.

Chairman HEINZ [continuing]. Since August 1984, you have had 16, 18, 20 meetings.

Dr. YOUNG. Sixteen, yes.

Chairman HEINZ. Sixteen meetings. And one of the purposes of those meetings is to decide what kind of information you need for the pacemaker registry. Now, for the life of me, I cannot see why that is so difficult and complex.

Dr. YOUNG. Let me try. It sounds incredibly bureaucratic to say we are still working on it. As you know, I have just come down to government 10 months ago from managing a medical center in upstate New York.

But these are the facts that I think must be looked at. We have to have a registry that is machine readable. There are approximately 16 firms that produce pacemakers and over 200 models. We have to be sure that we do not just punch in the information; we must retrieve it out again; we also have devices that have multiple parts. I brought one of these. As you can see, it is a relatively small device, but compared to the sinus auricular node that is within our own heart, it is huge. And not only does that have to be transplanted in, but we have the leads to go to this, and we have to document not only the parts and subparts within this, but the leads as well. We need information as to the physicians that have put these in, the hospital setting and, though it sounds simple, there is an incredible amount of programming that has to be put into place.

Also, it is important that we do not fire up a machine that is going to collect 200,000 reports per year—150,000 pacemakers and possibly 50,000 other components—and not have tested it in some sort of a pilot study to know that what we are doing is right.

So, accordingly, we went back to some of the other registries that are in place, the V.A. Hospital—and I will give you for the record some of the things that we found there. We found no registry that was already underway that we could adopt lock, stock, and barrel.

[Subsequent to the hearing, the following was submitted for the record:]

Review of Other Registries

VETERAN'S ADMINISTRATION PACEMAKER REGISTRY

The Veteran's Administration established a computerized registry of all pacemakers implanted in the Veteran Administration Hospital system in 1980. Subsequently they have added a monitoring function for in-use pacemakers and examination of explanted pacemakers which also feed information into the registry data base. After five years of data accumulation the registry contains usable data on approximately 88 percent of pacemakers implanted. The centralized monitoring system does not yet cover all pacemaker patients, although the participation is growing rapidly. The amount of information in the basic registry data base is now becoming sufficient for some brands and/or types of pacemakers that limited statistically based analysis can be performed. Utilization trend data which is available, however, will not be as useful as performance data, which is now beginning to accumulate, in identifying problems with pacemakers.

NATIONAL IMPLANT REGISTRY

The National Implant Registry was established in 1982 as a nonprofit organization providing a national information base regarding all types of implants. Their service also includes trend analysis and notification service for physician alerts and recalls. Pre-implementation development activities for the registry required two years, $200,000, and support from ECRI, which is a well established institution for the evaluation of medical technology. Despite this extensive investment in development of computer technology and the access to the hospital network created by ECRI, less than 1 percent of U.S. hospitals currently subscribe to the National Implant Registry. [Cost may be a factor in this low participation. Basic enrollment is $895, which includes up to 50 implant registrations. After the initial fifty, rates per implant range from $24.40 to $16.50, depending on volume.] Because of the low participation the data in this information base is not really useful for national trend or problem analysis.

BMD CONTRACT REGISTRY

The Cardiac Pacemaker Registry funded under contract by the Bureau of Medical Devices essentially allowed FDA to "piggy-back" on information which was already being collected. The time to implement the effort was subject only to the normal time sequence required to negotiate a federal government research contract. Costs and additional work involved primarily the work needed to put the information into a form usable to FDA and to provide some analysis and evaluation of the data by the contractor.

Dr. Young. So, although it sounds wooden and difficult, there are some decisions that have to be made in getting the data out. We could punch it in easily. But if we just punched it in, we would not be able to analyze it, and both of us would be very disappointed.

Chairman Heinz. I gather that you did examine the registries maintained by pacemaker companies?

Dr. Young. I looked at a number of them, sir. These are the ones that we studied. We looked at the Veterans' Administration Pacemaker Registry; we looked at a National Implant Registry that was established in 1982 as a nonprofit organization providing a national information base; we looked at the BMD Contract Registry to see whether we could piggyback on the back of those, as well—and I will provide the analyses for this. And we have put a substantial staff on this, trying to get the best possible registry.

I must also add that once we get the registry put together as far as the technical terms, then we need to go through some degree of rulemaking and interaction with the American physician community to make sure that we are getting the right information back, and we will do that in a pilot study.

Chairman **Heinz**. Dr. Young, you sound very committed to getting this registry operational.

Dr. **Young**. Yes, sir.

Chairman **Heinz**. What is your current timetable, before it will be fully operational?

Dr. **Young**. This is a difficult timetable to come to, because it depends on the degree of rulemaking. If we were to go in rulemaking in the normal fashion, there is a minimum of 180 days just by the time you complete the rulemaking process—the preliminary Notice of Rulemaking, the comments period, the analysis of the comments, and the rulemaking itself.

Chairman **Heinz**. Well, let me make it easier for you and just ask how close are you to getting to the beginning of any rulemaking process?

Dr. **Young**. I think that technically, we could meet the beginning of the rulemaking process in less than 6 months.

Chairman **Heinz**. In less than 6 months. So you are saying that——

Dr. **Young**. We will have the data——

Chairman **Heinz** [continuing]. By November or December of this year, at the latest, you will know exactly what information you need, you will know how to get it, and then sometime between now and there, you will decide on what methodology you will use, whether you are going to need the Administrative Procedures Act, or other legal methodology to actually implement and require the gathering of that information.

Dr. **Young**. This would be my goal. I want to be sure that this is very clear. This would be the fulfilling of the technical information that we need, and then we would need to go through the rulemaking.

And John, you feel that that would be appropriate, from your center's analysis?

Mr. **Villforth**. Yes; June 1986.

Dr. **Young**. So that this would enable us to then use the 6-month period after that for the rulemaking, and at the latest, we feel that by June 1986, we would have the complete rule in place. Now, that is our target, sir, but remember, I have added the 180 days into that, dealing with the rulemaking process itself.

Chairman **Heinz**. Dr. Young, in a memorandum, I believe addressed to you, from the Center for Devices and Radiological Health, dated March 15, 1985, it indicates that the Office of Management and Budget has had a great deal of influence on your ability to set up a registry.

Have you got a copy of the memorandum? Has that been provided to you?

Dr. **Young**. I do not have a copy in front of me——

Chairman **Heinz**. Staff will provide you a copy.[1]

Dr. **Young**. That would be very helpful.

Chairman **Heinz**. Could you elaborate on OMB's role in all of this and tell us what is now the status of the funding and personnel needed to establish the registry?

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[1] See appendix IV, p. 467.

Dr. YOUNG. I think that this relates, as I look at your highlighted portions, to resources that the Center was interested in and felt essential. The Center Director knows, and the staff knows, that I have made resources available from other programs within the agency, particularly from my own Commissioner's staff, and those resources are available.

Chairman HEINZ. I gather, though, that OMB did disapprove of resources being placed directly in that particular unit, sufficient to carry out the responsibilities of setting up the registry.

Dr. YOUNG. I believe that, as you said earlier, Senator, it is our responsibility to work with the budgets as prudently as we can and keep the deficit to an absolute minimum, and therefore, OMB recommended that I find ways to manage this and still keep our focus on some of the deficit problems.

Accordingly, I have been able to move some funds around and make those resources available to the Center.

Chairman HEINZ. Is something else important suffering as a result of that, do you think?

Dr. YOUNG. Well, we all have to make tough choices in these difficult times, and I have tried to keep any impact on operations to an absolute minimum.

Chairman HEINZ. You know, FDA is constantly criticized for being very slow.

Dr. YOUNG. Yes, sir.

Chairman HEINZ. Is this part of the problem, that you do not have the resources to do the job?

Dr. YOUNG. Let me see how I can best answer that. [Laughter.]

Chairman HEINZ. I am afraid you have opened a large bear trap, put your foot in it, and I do not know——

Dr. YOUNG. No. Let me try to answer it in a way——

Chairman HEINZ. I am not trying to trap you, but——

Dr. YOUNG. Let me try to answer it in a way that I think can be very constructive. At any time and place, we have to make difficult priority decisions. FDA touches upon 25 cents of every dollar that you and I spend—an enormous responsibility—cosmetics, drugs, devices, radiologic health, foods—and it oversees $450 billion of industry per year, in looking at public safety. In these, we have to make difficult priority choices.

I have been examining a plan of action that will help us meet some of the issues that you made reference to in regards to slowness of some of our actions, and I feel pleased to see that these will be forthcoming, and I think we can meet those commitments. But it is a tough time in the American financial scene, and the public health arena, and we have to do our best to order our priorities to stay within the mandate of budget that we have available.

Chairman HEINZ. Well, in view of a statement made on page 2 of the memorandum, which says, and I quote:

> Notwithstanding your recent offer to redirect five staff-years from your immediate office to the Center in support of this activity, we will still suffer a net loss of resources after the cuts planned for fiscal 1986 take effect. Thus, implementation of the registry legislation will require some compromise in our other statutory responsibilities in the device area.

What that really sounds to me like is that the budget cuts are compromising the ability of the FDA to safeguard the public health.

Are we robbing Peter to pay Paul?

Dr. YOUNG. Well, in one sense, we do have these difficulties. But we must, as an agency, deal with the distribution of any reductions that we have——

Chairman HEINZ. I sense that what you would like to say, except for the fear or the wrath of God who, in the executive branch, I suppose, is David Stockman, is "Yes, Senator, we are having a very difficult time meeting our statutory mandate to protect the public health, because the budget cuts and additional responsibilities that grow daily are incommensurate one with the other."

I have a sense that that is what you would like to say.

Dr. YOUNG. Well, a couple of small corrections, sir. I have no God that is a man, No. 1. So I would not fear any man as a God——

Chairman HEINZ. Well, then, let's change that to "Shogun."

Dr. YOUNG. But I do think that it is incumbent upon anyone working in government to work in the most prudent fashion in redirecting and directing funds. Thus, I have used funds, and what this memo refers to is the fact that each of us had to take cuts, and it looked difficult when I had to take away budgets in some areas, but specifically, took a harder cut myself in my own Commissioner's Office, and did add these resources directly to the Center. But it is a difficult time for any of us to meet our requirements that are increasing at times of diminishing resources.

Chairman HEINZ. Commissioner Young, in nothing that I am saying am I in any way intending to denigrate your sense of duty or your commitment to doing the right thing. To the contrary, I think you really do want to do the right thing. I think you are just getting a very rough time of it from people in the Office of Management and Budget. And you do not really need to answer my hypothetical question. The facts are plain. The facts are that you do not have the resources to do the job that you are statutorily mandated by Congress—and believe it or not, Congress does not mandate every good thing, or every necessary thing, or every helpful thing.

You know as well as I do that your agency is charged with not just doing specific things by Congress, but by meeting a much higher standard than just those things we tell you that you absolutely, positively have to do. So I respectfully submit to all, not just you, that the facts are plain; you do not have the resources to do the job.

This, however, is not the Appropriations Subcommittee on Health and Human Resources, chaired by Lowell Weicker, whom I imagine you will, if you have not already, will or have testified before. But if I sound a little bit like him on this particular issue, it is because I think we have both a deep concern in this area.

Let me ask you this. Does FDA have in hand a written commitment yet from HCFA to collect all of the data, including the warranty information, sufficient to fulfill the requirements of section 2304 of DEFRA, or is that something you do not expect to have until later this year?

Dr. Young. We do not expect to have all the full agreements, but we are working now on beginning draft documents and looking at how we can best make these agreements.

Chairman Heinz. And that is what you hope to have, in a sense, within the next 6 months?

Dr. Young. Yes. And we do have some of the material that I will submit to the record—on the second of May, we received the first draft of the regulations from HCFA, and on May 8, we had the second draft of the regulations from HCFA; and we are working through on this schedule, and we are working very rapidly with them.

Chairman Heinz. Is there anything this committee can do to be of help—or the Finance Committee, on which I also serve?

Dr. Young. I think one of the most important things that will come down the line are the issues that face us in this total, 100 percent registry. This is a registry that I have not had experience with. We are searching for 100 percent of the cases. We will need to determine how the information comes in, what sort of ways we can best analyze it, and I would be happy to keep you informed, particularly as we do the pilot studies. I would then be able to tell you much more specifically how you might be able to help, and I would be delighted to do so.

Chairman Heinz. All right.

One other thing. I know you missed the deadline for January 1 on the registry.

Dr. Young. Yes.

Chairman Heinz. Is there any reason that you could not have come and told us up here on the Hill that there was going to be a problem? Someone must have known that it was going to be a problem well before January 1.

Dr. Young. We did not communicate with you effectively on that and, knowing your interest in it, we should have. And we will keep you informed in the future. That was not appropriate on our part.

We were looking at a number of other analyses. We have been following the medical device reporting trends; we have looked at the variety of malfunctions of different devices, deaths, and serious injuries. This does not particularly relate to the case of registry that you are interested in, but we have broken down some of these and have analyzed the review of pacemaker—in this case, I am showing you deaths in relation to reports. So we have been analyzing this. I believe some of your staff are familiar with the type of reports that we have used.

We have put an awful lot of emphasis on trying to get this MDR reporting mechanism up. Some of it has been very useful. In a case most recently, when we had a problem with defibrillators, it was this registry that began to show us some problems, and we could see the increase in it, and then FDA dealt with it with a variety of actions that were very helpful.

So we have been very interested, and John Villforth has been exceptionally interested in getting good reporting information so that we can meet the needs of public health protection. But we did not notify you that we were having trouble with this. We should have. We knew that we were not going to make the deadline.

Chairman HEINZ. One last question on a different subject, but still in your area of responsibility, namely, that part you have identified as kind of your second responsibility, namely, monitoring the manufacture of devices. With respect to the FDA investigation at Cordis, a major manufacturer of pacemakers, you mentioned in your testimony that that company has made many improvements. Can you tell us whether or not the company is now fully complying with FDA regulations, and have all of the necessary changes recommended by FDA been implemented?

Dr. YOUNG. We are going to make the next inspection within the next few weeks to follow up on that, but they have been quite responsive to FDA. Just a short time ago, they destroyed approximately half a million dollars in parts that we felt did not meet some of the standards. And we have been making substantial progress on this. As you know, from the very fine staff work that you have, there has been a lot of activity at FDA, really trying to follow through on making sure that good manufacturing practices are followed, and I have been pleased with the intensity with which our investigators have worked.

Chairman HEINZ. When was the last inspection there?

Dr. YOUNG. I do not know off the top of my head the exact time——

Mr. VILLFORTH. The 19th of April.

Dr. YOUNG. The 19th of April, 1985.

Chairman HEINZ. The 19th of April, a little less than a month ago.

Dr. YOUNG. And we are due to be back within the next few weeks.

Chairman HEINZ. Let me ask—maybe I should properly address this to the gentleman to your right—as of your inspection on the 19th of April, was Cordis fully complying with all FDA relevant regulations, and have all of the necessary changes as of April 19th that you recommended earlier been implemented by the company?

Mr. VILLFORTH. They have assured us that they were moving in that direction, but we have still some actions that have to be verified, and that is one of the purposes of the inspection. There are still some applications to the agency for approval of products that they have made some modifications and changes on that are under review, and this has not been completed, so we will not know for some weeks until those reviews are completed.

Chairman HEINZ. Were they out of compliance with any FDA regulations as of April 19?

Mr. VILLFORTH. To the best of my knowledge, that is still under investigation, and we do not have the complete answer to that. They may be; we are still investigating that.

Chairman HEINZ. In terms of the necessary changes that the FDA required or recommended, I gather that while they may be making improvements, or at least going down the right path, there are a number that have not yet been implemented. How many are we talking about? What kinds of things are we talking about that have not been implemented?

Mr. VILLFORTH. I do not have the details on that.

Chairman HEINZ. Is there anybody here who does?

Mr. VILLFORTH. I think the field staff will be able to comment in more detail on that.

Chairman HEINZ. But they are not represented here?

Mr. VILLFORTH. Well, you will have an opportunity to talk to them in the next panel.

Chairman HEINZ. All right.

Well, Dr. Young, I want to thank you and your staff. You have been an excellent witness. I have no doubt that you really do intend to move along on this.

Dr. YOUNG. We do.

Chairman HEINZ. I am concerned that there is difficulty with the Office of Management and Budget, and your getting the necessary funds to protect the public health. I think based on the facts, not so much based on opinion—we operate on both here, sometimes too much the latter—that indeed, there have been difficulties on this program in the past. You may have remedied that to a certain extent, but something else is probably falling through the cracks, at least based on the information that has been provided to us. I know you are doing the best you can. I hesitate to urge you to work harder. I understand, however, that you are going to work harder. I understand you are going to move on to Assistant Secretary for Health shortly; is that right?

Dr. YOUNG. I do not know, sir. [Laughter.]

I read it in the papers every once in a while.

Chairman HEINZ. Well, it is certainly a promotion. I do not know whether it is a good thing or a bad thing. But if you do come up for confirmation before the Finance Committee, we will probably have another chance to discuss this. I hope it will not be necessary.

Dr. YOUNG. Well, it is a privilege to serve, sir, in any capacity, and I look forward to working with you, and I will be happy to keep you fully informed on our progress on this, by whatever types of reports that you would like, so that we can really see that this important issue is dealt with well.

Chairman HEINZ. Dr. Young, thank you very much.

[The prepared statement of Dr. Young follows:]

PREPARED STATEMENT BY FRANK E. YOUNG, M.D., PH.D.

Mr. Chairman, I appreciate the opportunity to describe for you today the progress we have made in establishing the cardiac pacemaker registry that is required by P.L. 98-369, the Deficit Reduction Act of 1984. This Act was signed into law in July 1984.

Under the new law, the Food and Drug Administration (FDA) must provide for a registry of all cardiac pacemakers and pacemaker leads for which payments are made under Medicare. The four expressed purposes of the registry are to assist the Secretary of Health and Human Services in (1) determining when Medicare payments for pacemakers and pacemaker procedures may properly be made; (2) tracing the performance of pacemaker devices; (3) determining when inspections of pacemaker devices by the manufacturer may be necessary; and (4) carrying out studies with respect to pacemakers of leads.

As we understand the intent of the legislation, the pacemaker registry is meant to be a mechanism to help contain costs and provide additional safeguards for Medicare beneficiaries. It stems at least in part from Congressional concerns that the Medicare program has been paying excessive reimbursements for pacemakers and pacemaker procedures. The registry is intended to provide the Health Care Financing Administration (HCFA) with a means of determining the warranty status of explanted devices and could also serve as a mechanism for determining the rates at which different makes and models of pacemakers are being replaced and the length of time that they are in service before being replaced.

The statute requires that whenever payment under Medicare is requested or made for a pacemaker procedure, the physician or provider of services must submit certain information to the registry, including the manufacturer, model and serial number of the device; the name of the recipient; date and location of the procedure; name of the implanting physician; name of the hospital or provider billing for service; and any express or implied warranties associated with the device. The information must submitted in accordance with regulations issued by the Secretary.

In addition, the Secretary may, by regulation, require providers to return pacemakers or leads which have been removed from patients to manufacturers for testing and that FDA personnel be present when a device that may have malfunctioned is being tested. Medicare payments may be denied for failure to comply with any aspect of either regulation.

PACEMAKERS AND FDA

There are approximately 500,000 to 600,000 people in the United States with implanted pacemakers, and about 150,000 new and replacement implantations are performed each year. The replacements occur for a variety of reasons, including routine battery depletion, the development of improved models, and patient symptoms that are suspected as being related to the performance of the pacemaker.

For most pacemaker wearers, the pacemaker is needed to support or sustain life only during isolated periods of time. However, approximately 20 percent of pacemaker wearers are always "pacemaker dependent," that is, they would suffer noticeable effects if their pacemakers failed. Most of these people would be limited in their activity by a lower heart rate and a general feeling of lethargy. A portion of these pacemaker dependent people—about 3 to 4 percent of all pacemaker wearers—would experience abrupt symptoms, such as dizziness or fainting, if their pacemakers failed. Roughly 1 to 2 percent of all pacemaker wearers would be at risk of death.

FDA regulates pacemakers by requiring manufacturers to demonstrate before marketing either that a pacemaker is safe and effective or that it is substantially equivalent to ones that were marketed before the enactment of the Medical Device Amendments of 1976. After marketing, FDA regularly inspects manufacturers and monitors reports of adverse reactions to ensure the safety and effectiveness of these devices.

Our recently-issued medical device reporting (MDR) regulations are designed to enhance our ability to spot performance problems that may occur with any marketed device, including pacemakers. These regulations require medical device manufacturers to report all deaths, serious injuries and malfunctions associated with these products to FDA. Our initial experience with the MDR program has been encouraging and indicates that this system will provide the information necessary to uncover serious safety problems. For example, MDR has already been effective in revealing a life-threatening problem with defibrillator batteries that were failing prematurely and without warning. This enabled us to send safety alerts to thousands of hospitals and emergency care facilities so that they could take immediate precautionary measures.

Since December 1984, when data first started flowing into the MDR system, we have received over 500 reports of possible pacemaker and pacemaker lead failures. However, as with any new data collection system, we have not yet received sufficient data to draw firm conclusions about whether the problems that have been reported are outside the range of normal pacemaker failures.

IMPLEMENTATION ACTIVITIES

Immediately after the legislation was signed in July 1984, we established an in-house task force within our Center for Devices and Radiological Health to develop an implementation strategy and to begin consultations with HCFA. A number of broad issues began to emerge, including:

How the registry could best be established and maintained;

How HCFA and FDA would collaborate in establishing and maintaining the registry and what the role of each Agency should be; and

How the data that would be generated could be used to fulfill the four statutory purposes for the registry.

Meetings between FDA and HCFA staff began in August. Our discussions with HCFA resulted in a preliminary implementation agreement and efforts are now underway to develop a more specific interagency working plan.

As the same time, our in-house task force started analyzing implementation issues, researching existing registries and estimating the resource requirements of implementing the registry. Several existing registries were researched to determine whether they already contained the kinds of information required by the statute. The task force concluded, however, that in their present form these existing registries could not supply all the information that was needed, although they could serve as models for our own registry in some respects. Moreover, with sufficient funding they could possibly be expanded to meet our needs and, in fact, several organizations have expressed an interest in this respect.

The information provided to us by our task force also led us to conclude that establishing and maintaining a registry in-house would pose substantial problems that might be resolved by contracting with a private organization. An in-house registry would require additional computer equipment and storge capacity, as well as specialized computer staff that might be difficult to obtain. Fortunately, a number of computer management firms, some specializing in cardiac pacemakers and leads, have brought their interest and capabilities to our attention, and we will be considering these and perhaps other organizations in the coming months.

Since a portion of the information required for the registry is already available through the Medicare payment system, FDA and HCFA agreed that physicians and providers should report the statutorily-prescribed information to HCFA through its intermediary network. Once collected by HCFA, the data will be sent to FDA, where it will be analyzed in such a form that it will be useful to FDA and HCFA. HCFA will be sent reports, probably on a quarterly basis. This agreement will allow us to implement the registry at a lower cost than was orginally estimated.

A memorandum of understanding between FDA and HCFA will be drafted to describe the responsibilities of both Agencies in greater detail. To accomplish this, a formal FDA/HCFA Pacemaker Registry Working Group has been established. Along with the memorandum of understanding, the Group is concerning itself with matters such as developing regulations, and identifying issues that still need to be resolved.

Developing regulations for the registry is to be a joint responsibility of FDA and HCFA with FDA assuming the lead role. The first regulation will be that required by law to establish the registry. It will specify the information that physicians and providers of services must submit to the registry as well as how and when they must do so.

The second regulation will address the return of the explanted devices to manufacturers, the testing of devices by manufacturers and sharing of test results with providers, and the circumstances under which FDA staff will participate in product testing.

I should note that as part of our efforts to design an effective registry system, we are soliciting views from affected groups outside the government. For example, we have discussed the proposed registry with a number of pacemaker manufacturers, which have formed a group under the aegis of the Health Industry Manufacturers Association. We will also continue to consult physician groups such as the American College of Cardiology, and the North American Society for Pacing and Electrophysiology.

The major unresolved issues involve the identification of each agency's data analysis requirements and, from our own standpoint, how the information from the registry will fit into the decision-making processes of FDA. The registry will better allow us to determine the rate at which implants and explants are occurring and to compare these rates among the different pacemakers. In addition, it will help to identify pacemaker wearers when problems are discovered. It remains to be seen how important this information will be in determining whether a problem relating to safety or effectiveness exists or in designing and implementing a solution.

We expect to analyze the registry data to determine gross performance problems, e.g., unusually high rates of premature device explants. We also can make use of this information to help confirm the MDR data concerning problems that may exist with particular makes or models. Once a problem is found, we will select a followup that is most appropriate for the situation and its potential for harm. Options include gathering more data, invoking the device return and testing provisions of the registry legislation to study the problem more closely, initiating an investigation of the manufacturer and manufacturing facility, or some combination of these. The results of these measures will help clarify the extent to which a problem exists and will aid in determining what regulatory actions should be taken to protect pacemaker wearers.

CORDIS CASE

In your letter of invitation Mr. Chairman you ask, among other things, for the status of FDA's investigation of the Cordis Corporation, a manufacturer of pacemakers. We have nearly completed our inspections of the firm. As a result of the inspections the firm has undertaken many corrective actions including the recall of certain products. We are now considering whether additional regulatory action should be taken in this matter.

CONCLUSION

In conclusion, we share your interest in assuring the safety of pacemaker wearers. Indeed, FDA believes that it is essential to provide the highest possible level of protection for all medical device users. To that end we continue to work with the regulated industry to assure adequate design and quality control procedures and have developed a mandatory reporting requirement for all manufacturers to report deaths, serious injuries and malfunctions. In addition, we are working with health professionals to encourage voluntary reporting of product problems. We believe that the pacemaker registry will contribute to our overall efforts in these areas.

We are carrying out cardiac pacemaker registry provisions of the 1984 Deficit Reduction Act. The planning and design that have gone into this effort thus far should help establish a reporting system designed to advise HCFA of possible reimbursement problems and assist FDA in confirming performance problems reported by manufacturers through MDR. Moreover, it should enable us to compare the problems reported against the total number of implants and provide data for more complete patient identification and follow-up.

That concludes my formal testimony, I will be happy to answer any questions you may have.

Chairman HEINZ. I would like to extend a very warm welcome to our next panel of witnesses who have traveled in some cases rather far to be with us today. As they are coming up, let me just observe that from my home State of Pennsylvania, we have Mrs. Wanda L. DeHart of Millersville, accompanied by Mr. Al Lewis, from Lancaster. Mrs. DeHart is a former schoolteacher and councilwoman.

Also, from California, Mr. Howard Bliss, all the way from Ojai, accompanied by Mr. Fred Bysshe, from Ventura; Mrs. Jacqueline Fischer, from Indian Harbor Beach, FL; and last, but not least, Dr. Brendan Phibbs, from Jackson, WY, who is at the University of Arizona.

I want to thank you for your patience. My questions of the earlier panel went a little longer than I had intended, but we are not too far from being on schedule.

I want to also express my appreciation for the traveling that you have done, for your being willing to tell us all of your personal experiences with failed or potentially defective pacemakers and leads. Sometimes, you know, in our oversight role here in Congress, when we discover problems, they tend to be statistical problems, and we forget that human lives, real people, are involved. And your testimony, I think, will be invaluable in documenting that this is not just a statistical difficulty, but it is all very real in how you and others are affected.

I know it is not easy to recount some of your experiences in public, so I am really doubly grateful and appreciative of your willingness to share your thoughts and feelings with us today.

I would like Mrs. Wanda DeHart, accompanied by Al Lewis, to please proceed.

STATEMENT OF WANDA L. DeHART, MILLERSVILLE, PA, ACCOMPANIED BY AL LEWIS, LANCASTER, PA

Mrs. DeHart. Thank you very much, Senator Heinz, for inviting us here to tell our side of the story, so to speak. So, that the Senator and others here will understand that I am no stranger to pain, and I know the different kinds of pain, in 1979, I suffered a heart attack which left me with considerable heart damage. In January 1980, I underwent triple bypass at York Hospital. At that time, there was no facility in Lancaster for that kind of treatment. In 1981, I underwent surgery, almost exactly a year to the day, for a kidney stone removal.

Now, this sounds unrelated—however, it was quite painful, and as a result of that, after the kidney operation, I began to feel ill, dizzy, and all of these symptoms that I had had before the heart attack. I had some consultation with a cardiologist in Lancaster, and he suggested that a pacemaker was needed—after he had eliminated the possibility of other problems. That was fine.

I underwent the surgery in February 1982. Having gone through surgery in the past, I understood that it took some time, perhaps, to recuperate from any kind of invasion of your body by a knife, and I suffered along with it for about a month or two, and it did not seem to be getting any better.

In fact, in April, it was getting much worse, and I was hospitalized. The pacemaker seemed to be working fine when I would get to the hospital or to the doctor's office. Again in May, I suffered these symptoms and went back to the hospital. Again, the pacemaker seemed to be working fine.

The monthly checks with the teletrace showed no indication that there was anything wrong with the pacemaker. However, the symptoms persisted, and worsened, until it came to this, that I was afraid to be left alone. I felt dizzy, light-headed; my pulse would get weak and thready; I felt as if I were falling.

In short, they were the same symptoms that I was experiencing before the heart attack. I kept nitroglycerine with me constantly. The major problem apart from the pain was the fear of not knowing when these things were going to strike. I could maybe go 2 or 3 days and nothing would happen, and then suddenly it would happen.

For instance, one night I was bathing, and suddenly, all of these things began to happen—the profuse perspiration, the pain spreading, light-headed dizziness—and that is not a very good place to have those symptoms. You could fall and kill yourself without having a heart attack there.

After that, I refused to take a bath unless my husband was in the next room, because I had this terrible—the word "anxiety" is used and has been used in connection with people who have had heart problems. Anxiety of any kind—it sounds like a very simple word. Frankly, I think it goes from anxiety to panic to terror.

When my husband would leave for work in the morning, I felt a feeling of terror of being alone, not safe. And my friends would call and ask me to lunch or to the theater, different places, and I could not accept their invitations because I did not know if I was going to be ill. Now, that sounds crazy, and that is exactly what happened—

people began to suspect that I was, and I also begin to think that perhaps there was a little something wrong—you know, hypochondria.

But again, I recognized these feelings of pain. The fact that the pacemaker was working properly when the doctor checked it over the telephone or when I was in his office did not indicate that the lead wire, which was eventually discovered——

Chairman HEINZ. What finally happened, Mrs. DeHart? You finally went to a hospital, did you?

Mrs. DEHART. I was in the hospital three times between the first implant and the second implant. That summer, my husband and I drove—they felt a change of scenery would be good for me—so we went to New Mexico. When we reached Colorado Springs, I was so ill that we did not tour the Air Force base as we had planned. I said, "We will go to your brother's house"—his brother lives in Alamagordo—and I went to the hospital there. I did not have any pulse. My husband took my pulse and could not find one, and he had been a hospital corpsman and was not unfamiliar with taking this kind of thing. But by the time I got to the hospital, the symptoms again had disappeared.

The doctor there called back and conferred with the doctor in Pennsylvania, the cardiologist. They determined that perhaps it was the altitude. So, we started driving east, and I thought, good, the closer I get to the east coast, the altitude will lessen and I will feel better. In fact, it got so bad that I thought I would not get home; I thought I was going to die.

We got back home. I went to the doctor immediately. I was on the EKG machine, strapped with all those things, and he said to me: "You have either just had a heart attack, or you are having one right now. Go straight to General Hospital. Do not go home, even to get a toothbrush."

I did that—and that was in early September—and the second implant was done that same day, in a matter of hours. I am talking about the lead wire.

Now, since——

Chairman HEINZ. What did the doctor diagnose—that there was a problem with the original lead wire?

Mrs. DEHART. I beg your pardon—I also have a bad ear.

Chairman HEINZ. I gather that the doctor who examined you back in Lancaster found that there was a bad lead wire; is that correct?

Mrs. DEHART. He did at that point. Apparently, sometime between the time I left for the trip and I returned, the thing had gotten so bad that when I got on the—I was in almost constant pain by this time—and when I got on the machine, this was when it showed up.

Chairman HEINZ. So, as I understand it, then, what happened was that the pacemaker was working correctly, but the lead was not?

Mrs. DEHART. Right.

Chairman HEINZ. And the lead was causing you to feel desperately ill, to the point where you said you thought you were going to die.

Mrs. DEHART. I really did.

Chairman HEINZ. When your doctor discovered that, I gather he felt it was a matter of some urgency, did he?

Mrs. DEHART. He felt it was extremely urgent. He told me to go immediately to the hospital, which was about a block or two away, from his office.

Chairman HEINZ. And right at that second—not tomorrow, now—right at that second.

Mrs. DEHART. No; right immediately, immediately.

Chairman HEINZ. So, he must have felt it was life-threatening. I understand that the lead that you had was a lead that had been recalled, and that it was a defective design in the lead that was causing the failure of the pacemaker to sufficiently regulate your heart; is that correct—or, Mr. Lewis—either one of you.

Mrs. DEHART. Well, I did not recognize that there could be a problem with the lead wire. I have two cards here. This was the first one, the identification card with the lead number; and the other came somewhat later, well over a year after the second implant.

Chairman HEINZ. What does the second card say?

Mrs. DEHART. It has a different lead number on it, 4002.

Chairman HEINZ. Whether you knew it or not, the original lead that you had had been recalled.

Mrs. DEHART. I did not know. I knew that only when my cardiologist called me the night before the story broke in the newspaper, because he did not want to have me very upset.

He said: "You did have one of those faulty leads. That has been corrected. The one you now have implanted is not faulty. You have a different number. So, you do not have to feel any anxiety about it." And of course, then, General Hospital called all of the people in who had had that number, and—and I use the word "replace" guardedly, because in many cases, they are not replaced; mine was not.

Chairman HEINZ. I understand. Yours was left in. It was very imbedded, I understand, and it was left in.

Mrs. DEHART. Yes; and I was told it would be very, very painful and dangerous to remove it. So, it was disconnected, and another lead was inserted.

Now, understand that you are awake all the time this is happening. You are not put to sleep. You watch it—you may even watch it on the monitor if you are ghoulish enough. I was not. It is bad enough to have to go through it once. The second time was really traumatic.

Chairman HEINZ. Mrs. DeHart, I thank you very much for some very helpful testimony.

I now want to call on the gentleman who has probably come farther than anybody else, Mr. Bliss, from Ojai, CA.

Mr. Bliss, I understand you would like to summarize your experience, and I have maybe one or two questions for you.

STATEMENT OF HOWARD BLISS, OJAI, CA, ACCOMPANIED BY FRED BYSSHE, VENTURA, CA

Mr. BLISS. Yes, thank you, Senator, for making it possible for me to be here so that I can hope to shed some light on the problems of what some of the recipients of pacemakers have had.

I will review a little history of how this happened, and I have a prepared statement here, and I may embellish upon it a little bit.

While on vacation in Idaho in 1980, I suffered a drastic slowdown of my pulse due to stress, which left me very short of breath. I checked into the Ashton Hospital in Idaho, which is a very small, one-doctor, 1,200-people-in-the-town hospital; however, I was very impressed.

After an examination, the doctor suggested that I stay overnight so they could run some tests. I was told that he actually could do nothing for me, that the pulse rate could not be speeded up with drugs. And so the doctor at the hospital suggested I might wait a week or two and see if my condition improved, if I quit working. My vacation place there was a place I owned, and I had been fixing it up, and the altitude was a little too much, and I think this was what perhaps brought it on.

So, after approximately a week, I decided there were no signs of improvement. I could not walk but maybe 15 steps, and would stop and gasp for breath. I could not do much of anything, and I am alone. I had no one else with me.

My son happened to be in the area at the time on a trip, and he had to leave. So, I made arrangements with my grandson in Ventura to fly up to West Yellowstone which was the closest airport, and he was picked up and brought down to my place, and we started packing to come home.

I went immediately to my doctor, who is an M.D., general practitioner. After examining me—this was in Ojai—he suggested that I see a cardiologist for further checking, which I did, and it was not entirely satisfactory to me his diagnosis.

So, I had had an experience with my wife, with the surgeon, a doctor in Ventura. She had some cardiovascular trouble, which happened to be terminal, but I was very happy with the thoroughness of the man. So, I made an appointment and went to see him, not realizing at the time that he was not a cardiologist; he was just a cardiovascular or thoracic surgeon. So, this time schedule goes on to December. After a lot of checks that he made, we decided that the pacemaker would be helpful to me. And so in December 1980, the original pacemaker was implanted.

Everything went fine, and I began to feel much better in a short while. In 2 or 3 months, I was feeling quite normal again.

I continued to have the pacer checked about every 3 months, sometimes by the cardiologist in Ojai, which the surgeon suggested I do, because as he put it, he was not a medicine doctor; he did only the operative procedures. And he also informed me that he had probably implanted 2,500 heart pacers.

So, I alternated between the two of them for my approximately 90-day checkups.

In July 1984, I went to the surgeon for a checkup, and he asked me if the cardiologist in Ojai had been in contact with me, and my answer was no. The surgeon then advised me of the suspect leads, and also showed me a copy of an AMA news item about them. He advised that I have them replaced within a reasonable period of time. And so, after thinking it over for a couple of weeks, I decided that was the way to go. So, a time was set for the operation, which was performed to change the leads which were suspect in August 1984.

Everything went fairly well except for the fact that the old leads were stuck in the vein and could not be removed. The new leads had to be inserted along the old ones, which meant that the old leads had to be capped off. To take care of the extra space needed, the generator pocket had to be enlarged quite a lot and left a rather large bulge in the chest area, that still is somewhat tender. I was also informed by the surgeon that while transferring the old leads and capping them off, to the new leads that had been implanted, that there was about a 5-second delay in getting the one final lead capped onto the generator, which was not removed at the time, and my heart stopped. I was aware of it at the time—this was done under a local—I had this sinking feeling, and they informed me that I was now 100 percent dependent upon the pacer.

I have had regular checkups since and am feeling sometimes up and sometimes down. I worry quite a lot about what is happening to the old leads in there that could not be taken out. I do not know what deterioration might take place, and when. Sometimes it worries me quite a lot. As I said, I live alone. I am trying to make the best of what is left.

Chairman HEINZ. Mr. Bliss, may I ask you a question or two?

Mr. BLISS. Yes.

Chairman HEINZ. I gather, in a sense, you were quite fortunate. Even though you were the victim of a lead that was recalled, that lead was prophylactically replaced by your doctor before any problems developed.

Mr. BLISS. Yes.

Chairman HEINZ. Mrs. DeHart, who testified just before you, was not so lucky. Her lead was already malfunctioning when it was replaced, and I gather, had your lead begun to malfunction the way hers did, given the fact that you were, according to your doctor, 100 percent dependent on the operation of your pacemaker, as evidenced by the fact that your heart stopped for 5 seconds, there is a fairly clear implication that, had what happened to Mrs. DeHart happened to you, you could actually have died, due to the failure of the leads.

Mr. BLISS. That is the impression I received from the doctor. He was happy that he made the decision, and I made the decision to have them replaced, because if they had ever shorted out, or one of them had gone bad, it could have been goodbye.

Chairman HEINZ. Your life could have been extremely jeopardized if the pacemaker, had failed earlier.

Mr. BLISS. That is right.

Chairman HEINZ. The other inference or lesson from your testimony, to my mind, is that the quality control over what manufacturers are doing cannot be too careful. And even if, as in your case, someone is lucky enough to have a deficient lead removed, nonetheless, that is still a very traumatic experience.

This is a photograph—do you recognize the person in that photograph?

Mr. **Bliss**. I am sorry—I do.

Chairman **Heinz**. Those are huge scars. And that is a picture taken after you had the defective leads—not actually removed, because they could not get them out—but you had to have new leads inserted.

Mr. **Bliss**. That is right.

Chairman **Heinz**. And that was really all you had done, as I understand. You just had the leads fixed.

Mr. **Bliss**. That is correct.

Chairman **Heinz**. They could not take the old ones out and put in some new ones. And that looks like a major piece of sculpture there on you. I gather it was a little painful, too.

Mr. **Bliss**. Well, a week later after that was taken, it was all black across the front.

Chairman **Heinz**. Well, I thank you for your information. I think it will drive the point home to people that when we talk about replacing leads, we are just not changing the batteries in a flashlight in a couple of minutes. This is major surgery. It is traumatic, it leaves lasting marks, and so much the more reason to make sure that when we do things right, we do them right not the second time, but the first time.

I thank you very much.

Mr. **Bliss**. Thank you for the opportunity.

Chairman **Heinz**. Our third pacemaker expert is Mrs. Jacqueline Fischer of Indian Harbour Beach, FL.

Mrs. Fischer, we are delighted to have you here, and we thank you.

STATEMENT OF JACQUELINE FISCHER, INDIAN HARBOUR BEACH, FL

Mrs. **Fischer**. Thank you, Senator Heinz. It is nice to be here today.

I developed a terrible infection called endocarditis, and it went undetected for almost 2 years. In August 1979, I had my first pacemaker put in. Shortly thereafter, we moved, but I went back to the doctor every few months, and I had a cardiobeeper, and I beeped them every month, in order that it was checked.

About 3½ years after it was put in, I went back to the doctor on one of those routine visits, and he told me that my pacemaker had lost 10 percent of its power, and I would have to have it removed. I was really shocked, and my husband was shocked, too, because just the visit before that, he had said that my pacemaker was a Demand Pacemaker and that it probably would last more than its projected 5 to 7 years.

Anyway, he said that it would be a 20-minute operation. Well, it was a terrible operation. It was 1½ hours, and as everyone here has said, it was under a local anesthetic, and I could see a clock out of the corner of the drape over my face, so I knew that it was taking a very long time. I finally asked the surgeon why it was taking so long, and he said that he had a rough time getting the pacemaker out, it was so covered with scar tissue, and then he said the leads were entwined, and they too had scar tissue, but he did not remove the leads. Then he said he had to fashion a new pocket in order to put the new pacemaker in—this was my second pacemaker—because it was a different size than the first one.

When I got back to my room a day or so later, and I was beginning to think about going back home, the cardiologist came in and he said that I would have to stay in the hospital because I had an infection and a fever, and he said I would have to have antibiotics intravenously until it went away. So I must have been there, I do not know, maybe 10 days or 2 weeks, and they finally said I was fever free, and I could come home.

Well, I found I was not fever free when I got home. I had shaking chills, and I had a fever almost all the time. The doctors at home gave me antibiotics, thinking I had a virus, or I had an infection, and they gave me antibiotics for that. At night when I would go to bed, I would have night sweats, and I would get up just soaking wet and have to change my nightclothes and put something down on the bed before I could go back to sleep.

This went on and on, all through 1983 and 1984. Finally, in April 1984, I got a call from the Pacemaker Data Center, who asked me if I still had in my original leads, number 6972 they were, and I said yes, I did. And they said, well, those leads had faulty insulation, and I should call the doctor and ask to have them removed, or ask him about them, anyway.

So I called the cardiologist, and he told me that if those leads were faulty, my pacemaker would have to work extra hard, and therefore it would fail prematurely. Well, what he failed to note was that the one that had failed prematurely was the one they took out the year before. This one was only a little over 1 year old, and it had not had time to fail.

So I continued along these same lines. Finally, I hemorrhaged a couple of times, and I was in the hospital, I guess as a result of the antibiotics. And, in September 1984, my husband took me to a restaurant, and this was kind of a rare occurrence, because I was so cold all the time that I could not go in a grocery store or a mall—and this was summer in Florida, when it is hot—without having a heavy sweater on. He took me to this restaurant, and I got such shaking chills that I had to wait out in the car while he finished dinner. I could not eat. And I told him to take me to the hospital.

The hospital ran blood cultures, and that is how they isolated the infection. They found that I had staphylococcus epidermis, which is staph-epi for short, and they told me that it probably had settled on the leads and in the pacer pocket, and that I would have to have the pacer and leads removed, that I would have to go back to the original site where they had put it in, have antibiotic treatment for 4 weeks, and then have a new pacer implanted at the end of that time.

So I did that. I returned, and at that time, they removed the pacer, and they removed the leads. And when the doctor took the leads out, he said they were cracked and brittle. Then I was in the hospital for 4 weeks with antibiotics, and that was terrible. My arms got all swollen from the needles every day, and they finally had to put a line down my neck in order to feed me the antibiotics intravenously that way.

And finally, at the end of 4 weeks, I was so dizzy I could hardly walk, and I had lost about 13 pounds, and they said, though, that it was OK if I came home.

I was home about 1 month, I guess, or maybe 6 weeks, when I noticed something was wrong with my right eye. I kept trying to wipe something away from it. I called the ophthalmologist, and when I went to see him, he said that I had a problem with the optic nerve, and he said it could have been caused by the endocarditis or the fact that the antibiotics I took were so toxic.

I am still terribly fearful. It was like a nightmare, those 2 years, and I really hope it will never happen again.

I thank you for listening to me today.

Chairman HEINZ. Mrs. Fischer, you really have had it all.

Mrs. FISCHER. It was terrible.

Chairman HEINZ. You went in for the initial implant. Then you had a problem with batteries, you had battery depletion, and that had to be fixed. Then they discovered that you had lead problems, so you had another operation, a third, for the removal of recalled leads. And then you have just described that involved with that was an infection, and you had to go in for another total replacement of leads and the pacemaker itself, and as a result, you not only spent a lot of time in the hospital, you not only had a staph infection, which is one of the most dangerous that you can; you may have had a loss of vision in your right eye, simply because of the stress of all of that, the physiological stress——

Mrs. FISCHER. Not only that. I was alone—I was 3½ hours away, so I was alone. My husband was home and I was away, and it was really a terrible experience.

Chairman HEINZ. What I think your case illustrates is that there are just extraordinary, serious, lifethreatening medical complications even if your heart is not 100 percent dependent on a pacemaker. If you have a fairly good heart and just need some smoothing out, you can still have life-threatening problems as a result of either leads or pacemakers not functioning properly.

So this panel as a whole has really demonstrated a series of different kinds of problems.

You are not unique. There are somewhere between 21,000 and 30,000 reimplantations of pacemakers each year. That is both good news and bad news. It is good news when a pacemaker that is coming to the end of its useful life is necessarily and properly replaced. Nothing works forever. We do not, and pacemakers cannot.

On the other hand, there are times when devices, particularly the leads, as we have heard, do not function properly; problems with them are not properly detected. If they are detected by the manufacturer, or FDA, the ability to recall them seems to be, at best, sluggish in all too many cases. People are not notified promptly. Doctors, fortunately, do at least call you ahead of time to let you know when the news release is going out, but by that time, it may be a little late.

What, in sum and substance—and I am going to call on Dr. Phibbs next—you have all really testified to is the fact that there needs to be a better system for keeping track of the ability of these devices, the proper manufacture of these devices, the timeliness of replacement of flawed devices, so that we really minimize the risk to people.

Let me call on——

Mr. LEWIS. Excuse me, Mr. Chairman.

Chairman HEINZ. Yes?

Mr. LEWIS. I wonder if I could just correct an inference in this hearing that bears specifically on the reasons for the hearing.

At the time of Mrs. DeHart's problem, there was no recall. In fact, our investigation showed, and so did the House investigation, that there was a deliberate effort on the part of the manufacturer to hide it from the public, hide the fact that they were having these problems. And no one knew why Mrs. DeHart and so many, many other hundreds and possibly thousands of people in the United States were having this problem.

It was only years later, 2 years, as an accident, really, in Lancaster, PA that some technicians in a hospital discovered it.

So I think it bears on the need for a registry such as you are talking about, so that there can be this computerized information-gathering and research.

Chairman HEINZ. Al, you are quite right. It bears on the need; it also bears on the urgency. Congress established the need by legislation quite some time ago. The registry was supposed to have been setup, as you know, by the first of this year. Therefore, the urgency is really highlighted by the kinds of problems we are talking about today. I thank you for making that point doubly clear.

Mr. LEWIS. Thank you, Senator.

Chairman HEINZ. Dr. Phibbs.

STATEMENT OF BRENDAN P. PHIBBS, M.D., JACKSON, WY, PACEMAKER CONTROL EXPERT

Dr. PHIBBS. Thank you for letting me reappear here.

First, I would like to congratulate the Senator and the committee—what you do not know is he has been working on your behalf for quite a while—and they have made significant inroads on what we perceive to be a major medical problem.

I would like to also say that I do not hate pacemakers; I love them. I was responsible for the first pacemaker implantation in the Northern Rocky Mountains a long time ago. They are miraculous, properly applied. They save lives, they sustain health.

Having said that, I must say that pacemaker technology is being abused and overutilized, at heavy financial and human cost.

I was part of a PSRO review. Three cardiologists independently reviewed 13 implantations in a small city recently, and independently reached the conclusion that 11; 11—were not necessary. Our findings were reviewed by the chief of cardiology at a major medical center, who confirmed it; so they are beyond argument.

In Philadelphia, a city not unknown to our chairman, a study has been completed which will be presented in Toronto at a major meeting on pacing in a few weeks. And, after reviewing many implantations there, they found that 15 percent were grossly abused. There was no reason to put the pacemaker in the patient. And 45 percent were questionable. And given the terms of that study, questionable means extremely questionable.[1]

Talking to my colleagues around the United States as recently as a seminar in Tucson last weekend, the situation has improved in some areas, but in many parts of the country, about one-third of the pacemakers being implanted are not justified by any medical standard, so it is a major consideration.

Now, there are both financial and human costs to this abuse. Even if only 10 percent of the 150,000 pacemakers being implanted annually were unnecessary, you are looking at a waste of $150 million.

Second, the human cost. Some data will shortly appear in a medical journal, which I had a role in collecting, pointing out that—what you have been hearing—about 2 percent of all pacemakers will be complicated by blood clots which form around the wire, and they break off into the lungs or back up into the brain.

Don't let me frighten you too much, Mrs. Fischer.

About 1 to 7 percent will be infected—like yours—and when they become infected, you must remove the wire, or the patient does not recover from the infection. And of course, the hooker here is they become adherent, as you pointed out, Mr. Chairman. Therefore, removal requires open heart surgery. A heavy cost.

Now, why is this overutilization going on? Two reasons. One is ignorance. I say that bluntly. I am on the Electrocardiographic Standards Committee of the American College of Cardiology, and we are concerned that the major flunk rate for our young cardiologists taking their board examinations is in the realm of cardiac arrhythmias and electrocardiography, the very skills you need to decide is someone needs a pacemaker.

We are addressing this by education, but it is a long-term process. Immediately, Mr. Chairman, you need standards promulgated—effective, tough-minded standards—uniformly around the country as an immediate answer to an immediate problem.

Second is, I hate to say, the financial rewards are inappropriate—inappropriately large. Testimony before this committee 3 years ago by a very competent thoracic surgeon from Colorado Springs established $500 as a very adequate fee for implanting a pacemaker, considering the modern techniques and time; it is plenty.

The fees range, in fact, from $1,000 to $2,000. They are comparable to gall bladder fees and major cancer surgery. They are based on the time when pacemaker implantation required open thoracic surgery, when you had to cut someone's chest open. Now, as you all know, they thread the pacer leads down a vein.

So if you applied a $500 saving to your 100,000 or 150,000 pacemaker insertions, you are again saving $50 to $100 million a year. So now we are up to about $250 million in savings, very realistically.

The new, more complicated pacemakers, dual-chambered pacemakers—these are electronic miracles when needed—but they are not needed that often. And there is a nasty incentive for implanting too many of these, and that is most of the surgeons charge about double fee for implanting a dual-chambered pacemaker.

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[1] See appendix V, p. 537.

Mr. Chairman, you mentioned $5,000 as the cost of a pacemaker. Out at my hospital, where I was chief, in Tucson, I negotiated hard for the simple type, and we got it under $2,000, $1,900.

If you cut down overutilization and take the profit motive out of the use of these more complicated pacemakers, you will save another $50 million.

Now, after the hearings last time, six of us got together and formed a national committee from Harvard to Washington to study the problem of utilization of pacemakers, and we evolved a set of guidelines—the indications for pacing in the slow heart rates. These were, I am glad to say, published in The Journal of the American Medical Association last September 15. Coincidentally, the American College of Cardiology and the American Heart Association appointed a committee some months later to study all aspects of pacemaker utilization. And they found almost substantially identical indications.

So, there are two committees of real experts—I can say this unabashedly—who have addressed this problem. Now, I met with a representative of HCFA here to go over the Medicare guidelines which, to all of us, have some obvious loopholes, and some potential for abuse. The medical representative agreed that these loophole potentials did exist. As far as I know, nothing has been done about it to change that.

So in conclusion, on behalf of a lot of concerned cardiologists, I have about three recommendations, Mr. Chairman.

First, we recommend that you establish precise and exhaustively worded guidelines for pacemaker insertion, based on the two committee requests available. And incidentally, we have had reprint reports from as far away as Moscow for these things. The rest of the world is very interested in these committee reports.

Second, implement a policy of second opinion review before anyone gets a permanent pacemaker. As a physician, I would be delighted to have a consultant come in; it would not hurt my feelings a bit. There is never an emergency implantation of a permanent pacemaker. You can always put in a temporary wire while you wait.

Third, cut the surgical fee to a reasonable number, that is, about $500, and pay the same fee whatever kind of pacemaker is being put in; it is still ample for the work.

And there is a tangential field that time does not permit me to get into, but it is in the prepared statement—the possibility that so-called electrophysiologic studies are being overutilized at considerable expense.

I will slow down and stop right there.

Chairman HEINZ. Thank you.

[The prepared statement of Dr. Phibbs follows:]

PREPARED STATEMENT OF BRENDAN PHIBBS, M.D.

First, as a physician I should like to congratulate the Committee. As a result of the previous hearings and of the continuing work of the staff, there has been a significant improvement in health care delivery in the specific context of pacemaker utilization in all its aspects.

The development of pacemaker technology has been a godsend, as all of us who practiced in the days before they were available are especially aware. I had the first pacemaker implanted in the Northern Rockies, in a patient of mine with severe heart block, and it was clearly lifesaving. I have remained close to the field, and have lectured to medical audiences nationally on the subject of indications for pacing and of conduction defects in the heart for years.

Significant problems persist, chief among them being overutilization. In a small Western city, as recently as last Spring, a PSRO review by three independent cardiologists, of whom I was one revealed that eleven of thirteen pacemaker insertions were unjustified. These findings were reviewed by the chief of cardiology at a major medical center, and confirmed; they are established beyond question.

Discussions with leading cardiologists in such centers as Los Angeles, Kansas City, various parts of Florida and elsewhere suggest that in many parts of the country as many as thirty percent of pacemaker insertions are unjustified. A carefully documented study from Philadelphia, soon to be reported at a major medical center found 15% of all pacemaker insertion to be totally unjustified and 45% questionable.

There is a high cost to overutilization. If only 10% of the 100,000 pacemakers initially inserted each year are not needed, the waste of health dollars will be $100,000,000.

The human cost is more serious. Data that will appear shortly in a leading medical journal summarize the complications of pacemaker insertion including a 2% risk of blood clots that may be catastrophic, a 1.7% possibility of endocarditis, or infection of the heart lining, which is fatal if untreated, and a possibility of openheart surgery to remove infected pacing wires. In addition, the patient suffers loss of insurability, limitation of employment, and a high incidence of psychological and psychiatric complications.

One of the reasons for overutilization is ignorance. I serve on the EKG standards committee of the American College of Cardiology and it has come to our attention that the highest failure rate in the cardiovascular board examinations is in the area of electrocardiography and disorders of heart rhythm—precisely those areas involved in the decision to implant pacemakers. The College is attempting to address this problem through education, but more immediately it is essential to promulgate reasonable standards and see that they are followed.

Second is the excessive fee paid for pacemaker implantation. This fee was set when implantation involved an incision in the chest and major surgery. Now the procedure has become greatly simplified and does not justify the $1,000 to $2,000 fee being paid. Previous testimony in 1982 by Dr. Bloom, a thoracic surgeon before this Committee made it clear that $500 is an ample fee for this procedure, which is often carried out by cardiologists with no surgical training. Reducing the surgical fee to this reasonable figure would save $50 to $100 million per year.

The more complicated dual-chamber pacemakers are electronic miracles, but they are being overused. The specific indications for these pacemakers are spelled out in the medical literature, but physicians seem to be prescribing these instruments indiscriminately.

Dual chambered pacemakers cost about $2,000 to $3,000 more than the simple types. The surgical fee is usually almost double, although the difference in time and effort especially with the newer techniques, is minimal.

Again, a waste of $30,000,000 or more may be involved. The Prospective Payment Assessment Commission study of pacemaker payments and practices contains an alarming misstatement in this context. It is claimed that invasive electrophysiologic studies are needed before implantation of these more complicated pacemakers. In fact, all authorities, including Dr. Furnan who testified before this Committee three years ago, agree that these complicated and expensive studies are virtually never needed to reach a decision about implanting a pacemaker. These studies involve placing three or four catheters within the heart, and a system of recording with very sophisticated electronic equipment. The physician's fee alone is $2,000. This is something like the $2,000 monkey wrenches in the defense budget. It is using an enormously complicated, expensive instrument to do what could be done with a five dollar tool—in this case, an ordinary fifteen dollar EKG.

At this time a State Blue Cross/Blue Shield organization is using a physician for some $4,000 for wrongful utilization of this type of study.

If these procedures are being reimbursed under Medicare, the cost may well be in the range of $50,000,000 annually.

As a result of the Committee hearings three years ago, a group of cardiologists organized a Committee to study and define indications for pacemaker implantation. I had the privilege of chairing that Committee. The study was published in the September 15, 1984 issue of JAMA, and requests for reprints of the article have come in from all over the world. Six months later the ACC and the AHA organized a joint Committee to study all aspects of pacemaker utilization and function. This Committee addressed the problem of indications in more limited form. The findings of the two committees were virtually identical. I personally went over the present Medicare guidelines with a physician who was representing the Health and Human Services Department, pointing out some serious loopholes that were major potential sources of abuse. Despite his apparent agreement on these shortcomings, apparently nothing has been done to correct them. It is fair to say that the Independent Study Report and the ACC AHA report include the opinions of some of the leading experts in the world.

On behalf of a number of concerned cardiologists, therefore, I should like to make several specific recommendations:

1. We recommend that you establish precise and exhaustively worded guidelines for pacemaker insertion, utilizing the two committee reports available.
2. Implement a policy of second opinion review before pacemaker implantation is authorized. Pre-review rather than post-review is essential if significant results are to be attained. There is, after all, no such thing as an emergency permanent pacemaker implantation.
3. Cut the surgical fee for pacemaker implantation to a reasonable figure such as $500. Pay the same fee regardless of type of pacemaker implanted, unless open thoracotomy is required.
4. Investigate the very real possibility that electrophysiologic studies are being overutilized in the study of heart block and related disorders, and implement corrective action.

SPECIAL ARTICLE

COMPLICATIONS OF PERMANENT TRANSVENOUS PACING

Brendan Phibbs, M.D., and Henry J.L. Marriott, M.D.

PERMANENT cardiac pacing, particularly by the relatively simple and safe transvenous method, must rank as one of the great cardiologic advances of the 20th century, with a record of thousands of lives saved and more thousands of patients relieved of symptoms previously beyond the reach of medical therapy. It would be wrong, however, to pretend that the procedure was innocuous; permanent implantation of a foreign body within the heart must always entail some risk, and before recommending or implementing permanent pacing, the physician must know what complications may arise and how likely they are to occur.

Data recorded in the world medical literature over the past 20 years make it possible to state the risk of such medical complications as thrombosis and infection in relatively precise quantitative terms. In addition, socioeconomic and psychological complications have emerged as important problems as larger numbers of patients with permanent pacemakers have attempted to live and function in modern society.

Medical Complications

Medical complications fall into three major categories: thrombosis and embolism, infection, and rarer complications, such as pacemaker-generated arrhythmias, myocardial perforation, and tamponade.

Thrombosis and Embolism

The risk of serious thrombotic or embolic complications is approximately 2 per cent. A relatively benign form of thrombosis of the veins of the upper arm and shoulder may be expected in about 30 per cent of patients with transvenous pacemakers; clinical manifestations such as edema of the arm or face will appear in only about 5 per cent.[1] Thrombosis of the axillary and subclavian veins is much more serious; the clinical course is often stormy, and anticoagulant and thrombolytic therapy is usually required.[2-4] Superior vena cava syndrome was detected in 4 of 1000 cases in one series; the syndrome has been reported to follow the formation of a thrombus around a broken pacing wire and fibrosis at the junction of the superior vena cava and the right atrium.[5-7] Cerebral venous thrombosis has been reported to follow propagation from a clot in the subclavian vein, with involvement of both transverse sinuses, a short distal segment of the straight sinus, the venous confluence, and the distal superior sagittal sinuses.[8] Thrombosis of the external jugular vein has been produced by a superfluous pacing wire that resisted removal by traction and subsequently migrated from the subclavian to the external jugular vein.[9] Large right-atrial thrombi are extremely hazardous; four cases of sudden death one to two months after insertion of the pacemaker have been reported. Death was preceded by intractable right-heart failure, and occlusion of the tricuspid valve by thrombus was postulated as the immediate cause of death.[10,11]

Pulmonary embolism, often fatal, complicating permanent cardiac pacing has been the subject of many

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case reports. Pulmonary emboli have been noted to arise from mural thrombi attached to a pacing wire in the right atrium or the right ventricle; one pathological study points out that thrombus formation along a pacing wire is the rule soon after implantation, with subsequent endothelialization of the clot around the wire.[12-18] It is clear that pulmonary embolism in a patient with a pacemaker should always arouse the suspicion of thrombosis on the pacing wire as the source.

The real dimensions of this problem remain to be defined.

Infection

Infection of the pacemaker pocket, the endocardial lead, or both, must be accepted as a predictable complication in a small percentage of patients with permanent pacemakers. Estimates of rates of infection vary from 1 to 7 per cent.[19,20] The infection may present as simple septicemia or as endocarditis.[21,22] The pacemaker pocket is the commonest site of entry, often with subsequent involvement of the pacing wire. Infection may also originate on the pacing wire itself or on adjacent traumatized endothelium. Infection of the pacing wire appears later than infection of the pacemaker pocket and has a more serious prognosis.[23,24] Large-scale reviews by Morgan,[25] Choo,[26] Grogler,[27] and Codini[28] and their colleagues, as well as case reports by Chavez and Conn,[29] Eichhorn et al.,[30] and Yarnoz et al.,[31] have yielded a consensus on the management of infected pacemaker systems. It is universally agreed that in the presence of infection the pacing apparatus must be removed; the mortality associated with infection if the pacemaker is not removed is in the range of 66 per cent. Since at least a third of the older types of pacemakers will become permanently entrapped in the ventricle,[32] thoracotomy is essential to remove the infected pacemaker and, in the opinion of all investigators, should be used without hesitation in this situation.

Other Complications

Rarer complications include constrictive pericarditis,[33] formation of painful contractile fibroblasts around the pacemaker pocket,[34] ventricular perforation,[14] tricuspid-valve insufficiency,[35] and reciprocating arrhythmias with some of the newer models of dual-chamber pacemakers.[36]

SOCIOECONOMIC PROBLEMS

Insurability

The question of the insurability of patients with pacemakers has been addressed in discussions with executives of insurance companies and by actual application on behalf of patients.

Life Insurance

No major life insurance company in the United States will provide a patient who has a permanent pacemaker with a standard insurance policy or standard rates. Such patients are invariably referred to special "high-risk" carriers; if they are accepted, the premiums are very high. This stricture also applies to special forms of life insurance, such as those included in mortgage arrangements or as part of tuition-payment loans.

Health Insurance

Applications on behalf of theoretical patients with pacemakers have been made to a number of health insurance carriers. It appears that no major health insurance carrier will accept these patients as individual applicants; some will accept them as part of a large group when "the risk is diluted." One state's Blue Cross organization reported the same restriction; a second stated that insurability would be determined "on an individual basis" after consultation with the patient's physician. Fortunately, many patients with pacemakers are in the age group covered by Medicare, but for those who are not, health insurance, in practical terms, is not available.

Employability

Federal antidiscrimination laws make employers reluctant to discuss limitations imposed by a pacemaker. Certain obvious exclusions include any work that involves flying or proximity to high-energy sources. Inability to qualify for required life insurance has presented problems in executive placement. To investigate the employability of patients with pacemakers, newspaper advertisements have been answered on behalf of theoretical patients, and industrial physicians responsible for employment policy have been interviewed. There appears to be a difference between professed policy and actual practice: on the one hand, employers are forced to give lip service to the "nondiscrimination" statutes, but on the other hand, many are apprehensive about hiring patients with permanent pacemakers and will seek reasonable excuses not to do so. The workmen's compensation laws in most states compel the employer to accept the patient "as is" or "as found" — i.e., to accept responsibility for any medical disability or dysfunction existing at the time of employment and for the consequences that may follow it. Although cliches about "finding a suitable niche for the handicapped patient" are commonplace, the truth is that the presence of a permanent pacemaker is a serious handicap in the job market.

PSYCHOLOGICAL PROBLEMS

In one of the earliest studies on the psychological implications of permanent pacing, Becker et al.[37] noted that of 97 patients, 55 responded normally to the implantation and were able to adjust satisfactorily, whereas 3 were severely anxious, 4 had evidence of a denial mechanism, and 7 were clinically depressed. Green and Moss[38] reported the reactions of 50 patients who survived longer than three months after implantation of a permanent pacemaker. They noted that 73 per cent had made an excellent short-term adjustment, whereas 27 per cent had marked symptoms of anxiety (described as "concern") or rejection of the necessity or desirability of the procedure. Blacher and Basch[39] studied 50 patients, 47 to 90 years of age, after permanent pacemaker implantation and noted three phases of adaptation: (1) preoperatively and while in the hospital the patients suffered a reaction to acute stress and were preoccupied with death and with medical terminology; (2) after discharge from the hospital, the patients' reactions varied with their basic personalities, fantasies concerning the pacemaker and its functioning emerged, and depression was common; and (3) after the pacemakers finally became integrated into the patients' daily lives, some ignored it, others centered their existence around it, and many expressed ambivalence. Serious postoperative depression developed in 12 patients and was attributed to feelings of loss of self-control and of independence. The highest risk of this complication was found in patients with previously independent and controlling personalities. Eight patients expressed a feeling of "being different," but the authors noted that this attitude was probably more widespread than was evident.

In describing a program to meet the psychosocial needs of patients with pacemakers, Hess[40] commented that after implantation "a substantial number" experienced difficulties in adjusting to their medical condition. Anxiety and depression were the commonest forms of psychoneurosis encountered. An organized program of skilled psychological support brought a considerable decline in adjustment problems within a year. Romirowsky[41] compared psychological adaptation in patients with pacemakers and patients who had undergone coronary bypass surgery. The patients with pacemakers could be differentiated from the patients who had undergone bypass by all psychometric dimensions studied. They were found to be more anxious, less expressive of aggressive feelings, more self-restricting in their leisure activities, and very ambivalent about the need for a pacemaker. They were less concerned about the actual surgery and more concerned about the problems of continued living. All psychological reviews stress the contrast between the effects of pacemaker implantation and of other types of heart surgery, such as valve replacement. In other types of heart surgery, the patient has the sensation of being "cured" of an illness, whereas in pacemaker implantation the patient is assured that the artificial device must remain in place for life, that frequent rechecks will be required, and that there is a possibility of battery or wire failure. This situation imposes a strain that many psyches do not find tolerable.

THE SPECIAL PROBLEM OF THE UNNECESSARY PACEMAKER

With these statistics in mind, the cardiologist is ready to confront a distressing problem — i.e., the patient who presents with a pacemaker that was needlessly implanted. A related difficulty is presented by the patient in whom a pacemaker has been implanted for an abnormality that proves on further observation to have been transient, with little prospect of recurrence.

The magnitude of this problem remains undefined, but several sources suggest that it is substantial. Chokshi et al.[42] noted the effect of peer review on pacemaker implantations in a major medical center. A set of reasonable criteria for permanent pacing were published and reviewed with the attending staff; the number of pacemaker implantations declined by 50 per cent over the subsequent two years. Selzer[43] compared pacemaker use in the United States, the United Kingdom, Canada, and Australia. He concluded that in the United States, "we use between two and three times as many pacemakers as prudence would indicate." Among other data he recorded the startling statistic that implantations for the sick sinus syndrome in the United States were eight times as high as in the United Kingdom, three times as high as in Canada, and six times as high as in Australia. Kowey et al. described the removal of 30 unnecessary pacemakers, commenting on the socioeconomic waste implicit in such abuse.[44]

We have had the opportunity to review a number of hospital files recording pacemaker implantation, some as part of the federally mandated Medicare peer review process, and others in the course of medicolegal assessment. In addition, because of the continuing interest in the subject of pacemaker use, colleagues have brought cases from a number of widely separated medical centers to our attention. On this basis it is possible to make several statements with confidence.

In a few localities as many as 75 per cent of pacemaker implantations have been found unjustifiable by any reasonable standards after review by several disinterested experts. The total figure for larger areas is certainly much lower, but in some regions and states it approximates 30 per cent.

Several groups of errors in diagnosis and prognosis recur prominently. Predictably transient abnormalities are often cited to justify pacemaker implantation before the acute process has had time to resolve. The ultimately benign depression of sinus-node function or of atrioventricular conduction that often accompanies inferior-wall myocardial infarction is an egregious example; the harmless, reversible sinus bradycardia that may attend or follow influenza or other viremias is another. Hypothyroidism is a prime example of an extracardiac correctable cause of depression of impulse formation or conduction that has led to inappropriate pacemaker implantation. Misinterpretation of the electrocardiogram is common. Nonconducted atrial premature beats are sometimes diagnosed as sinus pauses or Type II block; simple atrioventricular dissociation caused by the accelerated discharge of an ectopic pacemaker is frequently confused with complete atrioventricular block. Misunderstanding of the criteria for the diagnosis of Type II block seems to be widespread; confusion with 2:1 atrioventricular nodal block (Type I) is common.

Failure to exclude drug effects may be the commonest source of error. The sick sinus syndrome accounts for approximately 75 per cent of all pacemaker implantations in the United States, yet many physicians fail to appreciate the effects of drugs on the sinoatrial node. Digitalis preparations, quinidine, beta-blockers, calcium blockers, narcotics, some antihypertensive agents, and a number of psychotropic drugs can all depress sinus-node function. Elementary logic demands that the effects of such agents be excluded before sinus-node function is assessed, yet this obvious step is often omitted.

Drug-induced depression of atrioventricular conduction is often confused with intrinsic dysfunction or disease; the best example is the elderly patient with chronic atrial fibrillation who has a slow ventricular rate while receiving a digitalis preparation. Instead of discontinuing digitalis or lowering the dose, a surprising number of physicians have implanted a pacemaker for this iatrogenic, completely reversible abnormality.

If a physician thinks that a pacemaker may be unnecessary, he or she should review all records obtained before and after the pacemaker implantation, to see whether any valid reason for the original implantation existed. The native rhythm and state of conduction should be studied by means of Holter monitoring, treadmill testing, or both. If the pacemaker is programmable, it should be set at the lowest possible rate to allow a period of observation of the patient's native rhythm.

If the cardiologist is satisfied that there is no abnormality of impulse generation or conduction and no reason to suppose that any will ever exist, the entire apparatus should be removed. There are compelling medical and legal reasons for total removal of unnecessary pacing equipment. About 50 per cent of the older types of electrodes and practically all of the newer, long-tined electrodes will become permanently entrapped. A small but important proportion (at least 1 per cent) will become infected, necessitating removal to ensure the patient's survival. In the large percentage of these patients in whom the pacemaker is entrapped, removal will require cardiopulmonary bypass, with major morbidity and possible death. Failing to attempt to remove an electrode as soon as it is found unnecessary could reasonably be construed as falling below an acceptable level of practice, since such failure may expose the patient to a life-threatening intervention.

The power pack should always be removed, since it is a common source of infection and, furthermore, is often painful and always disfiguring. An attempt should be made to remove the electrode wire by simple traction. If the wire is entrapped, it may be removed by sustained traction with the use of weights. Although this technique has been successful, it has at times been complicated by avulsion of the tricuspid valve and other types of intracardiac damage.[45] Some surgeons prefer to cap the entrapped pacing wire and leave it in place, with appropriate warnings to the patient about the possibilities of thrombosis and infection.

Prophylaxis against endocarditis may be reasonable in the presence of an entrapped pacing wire. There are no data to support the effectiveness of such prophylaxis in this setting, but the documented incidence of endocarditis and the theoretical consideration that a permanently entrapped pacing wire constitutes a perfect laboratory model for its induction suggest that prophylactic measures are indicated. In terms of Venturi effects and lodgment sites, a permanently entrapped electrode presents as many hazards as most common valvular deformities.

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Mr. BYSSHE. Mr. Chairman, I would like to add a fourth recommendation with regard to the registry issue that is before this committee.

Chairman HEINZ. Yes.

Mr. BYSSHE. We found in Mr. Bliss' case—and I am the attorney representing Mr. Bliss in the litigation that ensued as a result of the defective pacemaker—that the serial number and model number were not accurately recorded in the surgical record or the doctor's own records. Because the efficacy and usefulness of this registry is dependent upon accurate information being inputted into that registration, it is important that you address, in terms of the regulations that are developed, a methodology to get accurate information into that record.

Doctors, nurses, support and clerical personnel are not bank tellers, used to dealing accurately with numbers. Their primary concern is the patient welfare; numbers are secondary.

My recommendation would be to require the manufacturers to imprint a label that would be a duplicate of the serial and model numbers of the implant device, whether it be a pacemaker, a lead, or any other apparatus; that that duplicate label could be torn off and inserted on your form number; further, that that duplicate label be machine and human readable. That way, you have a methodology that would eliminate the potential for error. The computer term, "Garbage in, garbage out", is no less applicable in computerese as it is in dealing with human lives.

Chairman HEINZ. Mr. Bysshe, I thank you very much for that suggestion.

On that, Dr. Phibbs, do you think that is a good suggestion?

Dr. PHIBBS. Indeed. You cannot be too precise in this setting.

Chairman HEINZ. It sounds excellent to me.

By the way, it is nice to have you back before the committee. You have not changed a bit in 3 years. You are just as full of life and go-getum as you were—you keep getting better with an extra year or two.

You did, in your last recommendation, just touch upon the need or the lack of need for electrophysiological testing. Now, these tests are relied on, I am told, for a lot of important information. I would like to know just briefly why the Prospective Payment Assessment Commission, [PROPAC], in particular—what you think, or other experts think, about PROPAC relying so much on that kind of testing.

Dr. PHIBBS. I was alarmed to see that in the PROPAC publication. Electrophysiologic testing, as you know, is an elaborate method of studying the electric activation of the heart. It is expensive and somewhat hazardous. You have to introduce three or four catheters from the groin, the neck and the arms, inside the heart itself, and you record the electric events of the heart on very sophisticated equipment. This is basically a research procedure.

There was some hope years ago that it might detect subtle forms of heart block. But the consensus now, includes the distinguished cardiac surgeon who testified at the last hearing, Dr. Seymour Furman, you may recall, who published an article last August in the American Heart Journal, saying he does not use these anymore to select patients for heart block.

Other equally prominent men have reached the same conclusion. All you need is an electrocardiogram recorded at rest and during exercise and some simple clinical horse sense. That is 99.9 percent.

At a major center like ours, we might use these studies once or twice a year. Yet they are being used, I think, very promiscuously.

Chairman HEINZ. In the case of, let us say, the 100,000 or so implantations that we have, how often would they be used—10 percent, 20 percent——

Dr. PHIBBS. We do not have a number on that, but I would certainly recommend that staff or somebody look at it, because you are looking at many millions of dollars being wasted. It is analagous to those $2,000 monkeywrenches over in the Pentagon. You are using a very expensive diagnostic mode for something that could be done with a $15 electrocardiogram. There is a big profit motive for administrators and physicians in overusing this method.

Chairman HEINZ. Once again, as you did 3 years ago, you have testified to the vast overutilization of pacemakers in hospitals, citing Philadelphia, where up to 60 percent either should not have been done or were questionable.

Dr. PHIBBS. Yes.

Chairman HEINZ. And you estimate still today, 3 years after our hearing, that still one-third of the pacemakers that are implanted do not need to be.

Dr. PHIBBS. By regions, yes. Now, in some cities, you have had an effect. I want to tell you that. In Albuquerque, NM, the cardiologists reacted to the hearings and to the publicity, and they have a strictly controlled system, and they are very effective. Others, it is carte blanche, spotty.

Chairman HEINZ. But on an average national basis, you would say about one-third?

Dr. PHIBBS. I would say, yes.

Chairman HEINZ. After the last hearing, some cardiologists apparently got upset at the results and documentation, and they conducted a study which repudiated the information received by the committee relating to the degree of overutilization, and recently, this study has been cited in the PROPAC report, the Prospective

Payment Assessment Commission's report, on pacemaker reimbursement.

I understand that you have looked at this study and have some information about it. What have you learned about this particular study?

Dr. PHIBBS. I am delighted to have the opportunity to comment. You remember that a study in a nearby State suggested that one-third of pacemaker implantations were inappropriate.

A prominent cardiologist in that State came forward with a report saying that the study was inaccurate, and only 1 percent were inappropriate—a figure that brought smiles to most cardiologists' faces.

We looked into his study, and it turned out that that cardiologist never looked at the charts himself. He concentrated on the small technical point that there was discrepancy between the discharge sheet diagnosis and the sheet within the chart—bad recordkeeping by doctors.

As for the decision as to whether the pacemakers were justified, he relied on the physicians in the hospitals that were criticized. They did their own in-house review.

Chairman HEINZ. Are you saying that his report was based on the opinions of the surgeons who did the work——

Dr. PHIBBS. Who were being criticized, yes.

Chairman HEINZ. In effect, they were criticizing themselves.

Dr. PHIBBS. Yes. They went out to the foxes and said, "Fellows, have you been picking on the henhouse?" and all the foxes said, "No."

Chairman HEINZ. Absolutely not.

I hope there is someone here from the Commission who will look into the appropriateness of using that kind of data to justify whatever it is they are justifying.

Now, you have made another recommendation which is to pay a single fee for pacemaker implantation; do not pay double for a double-chamber pacemaker.

Dr. PHIBBS. Yes.

Chairman HEINZ. Now, GAO found that it took 49 minutes of operating room time to implant a single-chamber pacemaker, and 79 minutes of operating time to implant a dual-chamber pacemaker. That would seem on the surface to indicate that we ought to pay more for a dual implantation.

Do you think that that study is right, wrong—how do we reconcile that with your recommendation?

Dr. PHIBBS. Well, first, that study is several years old, and techniques have again improved dramatically. The subclavian vein technique has made it quicker and easier to do. Most of the people doing these are not even skilled surgeons. They are cardiologists. And in Albuquerque, they are charging $480 for any kind of implantation today.

So that $500 is a generous fee when you compare it to what they pay for major abdominal surgery or major cancer surgery. It is a very generous fee, whatever they do, and it is a matter of minutes, 15 minutes plus or minus. It is a generous fee. I say that as an experienced employer of physicians, the head of a PC, the chief of staff at a hospital. That is plenty of money.

Chairman HEINZ. You are saying, I guess, that $500 would be an adequate fee for this procedure. What does Medicare pay?

Dr. PHIBBS. I was astounded to find they are paying $1,000 to $2,000—$2,000 on their list that we looked at. And that is as much as you pay to have your gall bladder taken out, which is a 1- to 3-hour major life-threatening procedure. It is more than a surgeon gets for removing a cancerous breast. It is as much as an orthopedic surgeon gets for a hip repair, a prosthetic hip, which is the biggest thing they do.

It is something of a joke among doctors. They all say, gosh, they set this back when it was a major thoracic surgery; now, it is a very minor procedure, and they are still paying us all this money.

Chairman HEINZ. Can you explain why the Health Care Financing Administration would not look into that, talk to a few doctors—maybe a lot of doctors—they have to do things—it takes them a long time to do something simple—and make this same discovery, that it does not take a long time to do a pacemaker operation. It is not the same as doing a radical mastectomy. Indeed, maybe doctors really are overpaid.

If you can figure it out, why can't they figure it out?

Dr. PHIBBS. I think you just paraphrased it—you said it takes a long time to do something simple, and that is true in certain quarters.

Chairman HEINZ. If you had Carolyne Davis' job, what would you do?

Dr. PHIBBS. I would change the fee schedule. I would get consultation with some responsible people. It would take about a day—a week, if you were dragging your feet—and I would have a new fee schedule out.

Chairman HEINZ. Would you be run out of town by the medical profession?

Dr. PHIBBS. No. The responsible elements know perfectly well what is an adequate fee. I think the others have a certain sense of guilt that would keep them quiet; I do not know.

Chairman HEINZ. Very well.

I must say, Dr. Phibbs, that you have the same gusto in your testimony that you do obviously in your practice, and everything else, as do all of our witnesses who have come a long way.

I see Mrs. DeHart has one last comment.

Mrs. DEHART. Yes, I do. I understand that the other people who spoke here are discussing Medicare payments. I have never been under Medicare care——

Chairman HEINZ. No; you certainly look nowhere close to 65.

Mrs. DEHART. These bills were paid by my husband's medical insurance, and I feel that this is an important part of it, too, because everybody shares in the cost rise. When someone who is not on Medicare suffers this many bouts of surgery, the fees, the rates go up. And in addition to that, at this point in my life, I am still young enough, I believe, that I could work, teach, do whatever I am capable of doing within the limits of my physical capabilities, and yet, what company would hire me? The insurance would be prohibitive to the company. I would not stand a chance of getting a full-time job anywhere.

Chairman HEINZ. Well, that point is well-taken. I guess about 90 percent of the implantations are paid for by Medicare; is that about right, Dr. Phibbs?

Dr. PHIBBS. YES.

Chairman HEINZ. You are one of the 10 percent of the implantations. But your point about the cost of unnecessary surgery, the cost of not properly diagnosing things, the cost of having to have a second set of leads—all of those costs are borne by somebody; even if it is paid for by Medicare, it is borne by the taxpayer, which is you, by the way; you, if you are working; by Al Lewis, if he is working.

So, every time someone makes a mistake, somebody else necessarily pays for it, even if the cost is being run through the Federal Government; it is still a waste, it is still a threat to your life or to Mr. Bliss' life or to Mrs. Fischer's. And I think that is really what you have all been so valuable in describing here today.

Mrs. DEHART. I realize that this is not pertinent to the cost, but it is not a very nice feeling to go to a swimming pool and have people staring at your scars, which are visible unless you revert to the 1928 style——

Chairman HEINZ. They are not in yet, at least according to Sports Illustrated.

Mrs. DEHART. Maybe a touch of vanity—I do not know about that part—but it is all part of the whole picture. When you cut in a place once, there is a scar. When you cut in that same place again, the scar becomes terrible looking. My goodness, it is a dreadful-looking thing. And then, of course, the lump underneath does not help, either, for the pacemaker—I am glad to have it there, believe me. I do not believe that my doctor made a mistake. I think he was absolutely correct in stating that I needed it.

Chairman HEINZ. Clearly. You were victimized by leads, essentially.

Mrs. DEHART. I believe that is absolutely correct.

Chairman HEINZ. Well, I want to thank all of you for your travels. We are so deeply appreciative of your telling your stories, which as I said at the outset, is not easy to do. It is nice of all of you to do us that kind of public service.

Thank you.

I would like Mr. Casey and Mr. Spanioli of the FDA to be our next panel. Then we will proceed to the FBI and GAO.

I understand that the FDA investigators are accompanied by Mr. Donald Biers of the FDA's Office of General Counsel.

Let me just say that the two gentlemen, Mr. Casey and Mr. Spanioli, have been associated with the FDA's investigation at the Cordis Corp. beginning in early December 1983.

Gentlemen, on behalf of the committee, I welcome both of you, together with your counsel, and want to compliment you on your investigative work. Prior to our questioning you, the FDA has asked me to state that an investigation of the type conducted by the agency at Cordis could ultimately result in a decision by FDA to recommend to the Justice Department that legal action be taken.

This committee, of course, does not in any way wish to interfere in matters of that kind. Therefore, I would urge all present and any committee members that might decide to attend to refrain from asking these two witnesses for comment on potential legal ramifications of the conditions they have observed at Cordis.

Also, I wish to make clear that Mr. Casey and Mr. Spanioli are appearing here today under subpoena issued by the chair of this committee to answer questions relevant to the purpose of this hearing.

Gentlemen, would you mind please rising, stand, raise your right hands—do each of you swear or affirm to tell the truth, the whole truth and nothing but the truth, so help you, God.

Mr. BIERS. I do.

Mr. SPANIOLI. I do.

Mr. CASEY. I do.

Chairman HEINZ. Gentlemen, thank you. Let the record show that all the witnesses responded in the affirmative.

Mr. Casey, your records show that the FDA investigation at Cordis Corp. began on Saturday, December 3, 1983, 1 day after your office received a call from the company. What was that phone call about?

STATEMENT OF JAMES CASEY, MIAMI, FL, SUPERVISORY INVESTIGATOR, MIAMI RESIDENT POST, FDA, ACCOMPANIED BY VICTOR SPANIOLI, INVESTIGATOR, AND DONALD BIERS, COUNSEL

Mr. CASEY. Mr. Chairman, the phone call was concerning the Cordis Corp. intended notification involving approximately 10,000 pacemakers referred to as Gamma pacemakers, due to an early battery depletion problem.

Chairman HEINZ. And they had mailed that out as an urgent medical device notification; is that correct?

Mr. CASEY. They were notifying us that they intended to mail it out, which is customary, and in this particular instance, the notification had already been printed, and it was mailed out the following Monday.

Chairman HEINZ. Now, does the fact that there was a notification of early battery depletion mean that the batteries in some of these pacemakers were going dead sooner than they should have?

Mr. CASEY. Yes, sir.

Chairman HEINZ. Mr. Spanioli, there are 34 pages of findings that you presented to the company in April 1984, and we have provided you with copies. You state in finding number 46 [1] that approximately 6,327 pacemakers which incorporated cells with unprotected feedthroughs were distributed from November 1980 through August 1983 "after the Gamma cell design was improved"—that latter phrase is a quote.

Were all 6,327 of these pacemakers subject to the problem of early battery depletion, and if so, how many of these pacemakers have failed prematurely?

Mr. SPANIOLI. The entire population of Gamma pacers that had unprotected feedthroughs as I described here were subject to the same failure mechanism.

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[1] See appendix VI, p. 606.

As to the number of these 6,327 that failed as a result of early battery depletion, I do not have that information.

Chairman HEINZ. I am advised that as of April 1, 1985, that the company informed FDA that there were a total of 2,053 implanted Gamma pacemakers containing these earlier batteries that failed prematurely. Is that the information that you have?

Mr. SPANIOLI. That would include the pacemakers that were distributed prior to the modification being made in November 1980. That would be correct as to the entire population of pacers.

Chairman HEINZ. In finding number 26 again, Mr. Spanioli, you state, quote:

> As of February 1984, there were a total of 270 expired patients that had Gamma pacemakers subject to the December 1983, Gamma notification," and that, "Prior to this inspection, no effort had been made to determine that the recognized pacemaker early battery depletion failure problem could have resulted in a patient death that might have mistakenly been attributed to nonpacemaker-related causes because a physician had no reason to suspect early pacemaker failure.

Now, we had a witness a moment ago, Mr. Bliss, who discovered that he was entirely dependent on the proper functioning of his pacemaker. We had another witness from my own State, Mrs. DeHart, whose experience was that she was, in fact, having failure of the pacemaker leads.

Could you explain to us the meaning of your particular finding?

Mr. SPANIOLI. This was a perception that I raised with regard to the possibility that despite the fact that the firm may not have received any complaints or any reports with regard to a patient expiration being associated with a pacemaker malfunction, it was my judgment that there was sufficient cause to have the firm consider the possibility that there may have been a cause-and-effect relationship.

Chairman HEINZ. So here, we have 270 patients that died. They had pacemakers that everyone had reason to believe were not working the way they should. And what you are saying is the company made no investigations of any of these 270 deaths to determine whether or not there was a mistake by the physician in the cause of death; they did not do anything about that?

Mr. SPANIOLI. That is correct, at the time of the inspection. Subsequently, they looked into this further.

Chairman HEINZ. At that time, did the company have reason to consider investigating these deaths? Did they have any data or study findings pertaining to the battery problem that might have prompted them to want to investigate these deaths?

Mr. SPANIOLI. Not based on the records that were made available to me by the company. There was no indication that these deaths may have been associated with pacer malfunctions.

Chairman HEINZ. Now, you use the term, "not based on the information that was made available to you at that time". Was there other information?

Mr. SPANIOLI. I have not become aware of any other information.

Chairman HEINZ. It is my understanding that the company had begun a study[2] in October 1980 involving 200 Gamma battery cells. That study was terminated 2 years later, October 1982, and apparently, there was no written report of the study prepared by the company. However, as a result of pacemaker failures in mid-1983 attributed to early battery failure or depletion, the data from this study was resurrected and evaluated. There was no explanation as to why the data from the 1982, 200-battery cell study was not evaluated until the middle of 1983.

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[2] See appendix VI, p. 575.

And as I understand it, this is, I believe, an inspection report by yourself, Mr. Spanioli—is it not?

Mr. Spanioli. Yes, sir, it is.

Chairman Heinz. And doesn't it say essentially what I just said?

Mr. Spanioli. That is correct.

Chairman Heinz. How does that square with your earlier statement that the company had no reason to investigate these deaths?

Mr. Spanioli. I was referring to the fact that, to my knowledge, the company had not received any complaints from physicians that specified that the pacers had malfunctioned. Based on my findings, there was no reason to believe that those pacers had, in fact, malfunctioned. There was the potential for malfunction, and that was my concern at the time of the inspection.

Chairman Heinz. What about the internal documentation by the company?

Mr. Spanioli. I am sorry, I do not understand your——

Chairman Heinz. Well, your point was, as I understand it, that the company had not received any external complaints from doctors that would have caused them to investigate. On the other hand, they had already started investigating themselves.

Mr. Spanioli. That is correct.

Chairman Heinz. And that is what I mean by internal information, internal documentation.

What they apparently found, and what you have confirmed, is that there was a predicted mean time to failure extrapolated to 37 degrees Centigrade, body temperature, which is 32 months. These pacemakers were in longer than that. A problem—no?

Mr. Spanioli. There are a couple of aspects. Specifically, with regard to the company's failure to follow up on the patient deaths, one could make the argument, as I presented in my findings, that they had an obligation to pursue those deaths, even though they had no reports of any adverse reactions or any connection with the deaths and pacer malfunctions.

As far as the 200-cell study is concerned, that was a very significant observation, and——

Chairman Heinz. How long, according to the company, were the batteries supposed to last?

Mr. Spanioli. They vary with the model type. On the average, they are designed to last between 7 to 11 or 12 years, depending on how they are set.

Chairman Heinz. And yet here, the mean time to failure was 32 months, less than 3 years. Am I interpreting the information correctly?

Mr. Spanioli. This is based on a special study. It does not necessarily reflect performance at body temperature. This is a study that involved 200 cells that were placed at different temperatures. The data that was obtained and subsequently analyzed in mid-1983 showed a correlation of the failures that they had at elevated temperatures with a theoretical failure (mean time to failure) at body temperature, which is what you stated, 32.1 months.

Chairman HEINZ. Mr. Casey, do you have any comment on this particular situation?

Mr. CASEY. Mr. Chairman, maybe I can clarify it a little bit. The fact of the matter is that if the 200-cell study had been evaluated timely and properly by Cordis, I think their evaluation of the early battery depletion problem could have been recognized much sooner than before August 1983.

In regard to following up on expired patients, unfortunately, oftentimes, the pacemaker is buried with the patient. Therefore, it is difficult to follow up on these. And I have to qualify this as an opinion, sir, but I believe it is common practice throughout the pacemaker industry not to follow up on patient expirations unless they receive a report from the physician or hospital, or possibly, their own salesman, as to some adverse consequence associated with that death.

It is difficult to say that because of the 200-cell study, that they should have followed up on all these patient deaths. To say that as a matter of practice they should be concerned enough to follow up on any patient death, I think that is a judgment value that the audience can make themselves.

Chairman HEINZ. If you had been handed on October 3, 1980, the study that we were just talking about, Mr. Spanioli and as a professional in the field charged with protecting public health and safety, would you have done something based on that report if it had come into your hands back on October 3 or 4, 1980?

Mr. CASEY. As a point of clarification, I believe that was when the study was started. If we had been provided interim results that showed adverse battery depletions based on that study, we would have promptly begun an inspection.

Chairman HEINZ. Now, Mr. Casey, prior to your investigation, FDA had received from an anonymous source an internal Cordis report titled, "Special Audit: Gamma Battery Cell Depletions", dated September 22, 1983.[3] Do you have a copy of that?

Mr. CASEY. Yes, sir.

Chairman HEINZ. Is this a copy of the Cordis report that FDA received anonymously?

Mr. CASEY [perusing document]. Mr. Chairman, I do not believe it is.

Mr. SPANIOLI. I do not believe it is, either; it is not.

Chairman HEINZ. Do you have one similar to it?

Mr. SPANIOLI. The copy that we have is the one that was obtained from Cordis.

Chairman HEINZ. Did you not receive one anonymously before you received one from Cordis?

Mr. CASEY. Yes, Mr. Chairman, we did. The primary difference is that this one is annotated with margin comments and so forth, and the one that the agency received was not.

Chairman HEINZ. But otherwise, they are identical?

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[3] See appendix VI, p. 575.

Mr. CASEY. Yes, sir.

Chairman HEINZ. So you had the nonannotated version of this?

Mr. CASEY. Yes, sir.

Chairman HEINZ. Anonymously. OK.

Briefly, what did it indicate?

Mr. CASEY. If I may, Mr. Chairman, I will refer this to Investigator Spanioli. He is more intimately familiar with it, and if I can help, I will be more than happy to.

Chairman HEINZ. All right, whoever; what does the report indicate?

Mr. SPANIOLI. The report basically summarized the problem with regard to premature battery depletions regarding Gamma pacers. As part of the firm's investigation, an audit of the battery manufacturing plant was undertaken to try to determine what was causing these failures, and the report summarizes the findings of that audit.

Chairman HEINZ. And is it or is it not accurate that it summarizes that there had been 134 premature Gamma battery depletions as of 9-22-83; that about 65 percent of the failures were from battery lots manufactured over a 9-week period in mid-1980; and that there are many process anomalies in the suspect time frame to indicate an overall lack of control?

Mr. SPANIOLI. That is correct.

Chairman HEINZ. Mr. Casey, after you began your investigation in December 1983, did either of you ask the company for a copy of this report? I guess the answer is "Yes", is it not?

Mr. CASEY. That is correct.

Chairman HEINZ. What were you initially told by the company?

Mr. CASEY. We were initially told that all internal audit reports, as a matter of corporate practice, are destroyed.

Chairman HEINZ. They were destroyed. So this report that we have a copy of was routinely destroyed, they said, by the company.

Now, we are providing you with a copy of a document [4] dated September 22, 1983. Is this the company's record of the destruction of the report?

Mr. CASEY. Yes, it is.

Chairman HEINZ. What did you tell the company after receiving this, and how did they respond?

Mr. CASEY. We informed the company that we thought the special audit, internal audit report, was in our interpretation a follow-up to a device failure or a defective device, and therefore, that it should not be destroyed and that we were entitled to see it.

Chairman HEINZ. Did you tell the company that you would consider the failure to supply a copy of the report as an inspectional refusal? [5]

Mr. CASEY. Yes, we did.

Chairman HEINZ. Then what happened?

Mr. SPANIOLI. Subsequently, we did obtain a copy of the special audit report from the company.

Chairman HEINZ. The company gave it to you. They told you they did not have it, that it had been destroyed, they proved to you it had been destroyed; you said, "Sorry, that is not good enough; we are going to cite you for an inspectional refusal"; and then they provided it to you?

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[4] See appendix VI, p. 598.

[5] See appendix VI, p. 608.

Mr. SPANIOLI. That is correct.

Chairman HEINZ. That is pretty clear. They lied, and then they were proved to be a liar.

Mr. Casey, a document in the possession of the committee indicates that a Cordis official informed you and Mr. Spanioli, in a meeting in February 1984, that the company was considering a policy to prevent audit reports on specific product failures from being destroyed in the future.

Do you know if the company has adopted this policy since that meeting?

Mr. CASEY. No, I do not.

For the record, I might add that within the past month, we have requested a copy of the internal audit that they did, conducted as a followup to our October-November comprehensive GMP inspection, and they told us—we were informed—that we did not have the authority to obtain a copy.

Chairman HEINZ. Mr. Spanioli, FDA records show that on December 3, 1983, you asked the company for any and all documents pertaining to the formation of an internal Cordis task force that had been established in the summer of 1983 to study the early failure problem with the Gamma battery. Is that correct?

Mr. SPANIOLI. Yes sir, it is.

Chairman HEINZ. Could you briefly tell us what happened as a result of your request?

Mr. SPANIOLI. Later on, during the inspection in December of 1983, I received a one-page memorandum [6] dated August 19, 1983, regarding the formation or the establishment of the task force.

Subsequently, I asked to see the task force memorandum at the battery plant, this would have been in January of 1984. At that time, I again was shown the same one-page task force assignment memorandum with the August 19, 1983 date.

The following day, I was told that this memorandum had been revised. The original memorandum, with the August 19, 1983 date, was a two-page memorandum,[7] and that was subsequently provided to me on that date, with an explanation of the circumstances regarding the two different August 19, 1983 task force memoranda.

Chairman HEINZ. So you originally were provided with an altered version of an original memorandum with an explanation as to why you were provided with the wrong document.

Mr. SPANIOLI. Originally, I was provided with a one-page memorandum; that is correct.

Chairman HEINZ. Well, we are providing you with a copy of a two-page memorandum dated August 19, 1983, and with a copy of a one-page memorandum, bearing the same date, both entitled "Gamma Cells and Gamma Pacers Task Force".

How does the original differ from the altered version of the memo?

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[6] See appendix VI, p. 572.

[7] See appendix VI, p. 573.

Mr. SPANIOLI. The original appears to include eight paragraphs, each of them are numbered, 1 through 8, that describe some of the background investigative work that the firm had undertaken with regard to the cause of their Gamma early battery depletion problem.

The initial one-page version I received does not include those eight areas.

Chairman HEINZ. It is interesting, isn't it, that in the memorandum you were provided with first, the first paragraph appears to be exactly the same, typed word-for-word, and then, it simply degenerates, the altered version, into some generalities; whereas the original version, the one you did not get the first time, as you mentioned, is quite specific, eight separate instances of a genuine problem.

Take one of those problems, the average implant time to depletion is approximately 30 months. That is the battery we are talking about—30 months; the range is somewhere between zero and 35 months. And this is on a product where, as you said earlier, the expected battery life is between 7 and 11 years. And so it goes on down through the list.

What reasons did the company officials give you for providing you with an altered version that deleted the eight items of information concerning the battery problem?

Mr. SPANIOLI. The reason that was presented to me by the individual who prepared——

Chairman HEINZ. Well, what was the initial reason they gave you?

Mr. SPANIOLI. The initial reason—this was a documented explanation, a written explanation—for revising the memo was to more clearly define the basis for the formation of the task force.

Chairman HEINZ. Did anybody tell you anything else later about why there had been an altered memorandum?

Mr. SPANIOLI. In a subsequent conversation with a corporate officer, I was informed that the reason was clear, that it was to minimize the examination of the investigation that Cordis had conducted in trying to identify their battery problem.

Chairman HEINZ. What you are saying is if you got the original memorandum, they were afraid FDA would really look into the matter, and they did not want you to; is that what that really means?

Mr. SPANIOLI. That would be correct.

Chairman HEINZ. Mr. Casey, FDA records show that in early summer of 1984, the FDA discovered a wiring defect problem in another group of Cordis pacemakers, certain models of the Lambda, Theta and Stanicor devices; is that correct?

Mr. CASEY. That is correct, sir. I believe it was a little bit before the summer.

Chairman HEINZ. Very well. Could you describe how this wiring problem affected these pacemakers and how many of the devices were involved?

Mr. CASEY. The printed wiring board was subject to vapors within the pacemaker. As a result, the printed wiring board had holes in it. As a result, the vapors would cause the board to separate, and therefore create a short. Insofar as a pacer-dependent patient is concerned, this means that the pacer would go to a sudden, no output, failure mode and the pacer would not operate, in certain instances. The pacer-dependent patient would be at risk.

Chairman HEINZ. How many of those devices did you find the company to have distributed?

Mr. CASEY. I believe they may have distributed—and please forgive me for not being specific, but I cannot be at this time—somewhere between 30,000 and 37,000 pacemakers.

Chairman HEINZ. Has Cordis issued a recall on these pacemakers and notified physicians of this problem?

Mr. CASEY. They have notified physicians of the problem on selected models where both in-house testing or field failures have been confirmed with the printed wiring board problem. The notification involves approximately 28,000 pacemakers which we believe may be implanted at this time.

Chairman HEINZ. Now, here are a large number of pacemakers. You have just said that they could fail in the case of some of the people who are dependent on pacemakers. That could be a fatality in their case, if they were 100 percent dependent.

What were the physicians told to do with patients having these pacemakers?

Mr. CASEY. For pacer-dependent patients, the physicians were advised in the notification issued in April of this year to prophylactically replace the pacer.

Chairman HEINZ. Finding No. 46 [8] on this issue, Mr. Casey—and we have provided you with a copy—appears to indicate that the company corrected the wiring defect in September 1980, but failed to rework those already in inventory and continued to sell them until the summer of 1983.

Could you explain this and tell us the total number of pacemakers involved in that?

Mr. CASEY. OK. The statement, Mr. Chairman, that you made is true; however, I do not quite understand what you want me to explain about that action.

Chairman HEINZ. How many pacemakers were there?

Mr. CASEY. Approximately 2,200 pacemakers were shipped out between September 1980, when they corrected the defect in the printed wiring board, and the summer of 1983.

Chairman HEINZ. So it is a reasonable inference that the company knew that they had these defective pacemakers, but shipped them out, anyway; is that a reasonable inference?

Mr. CASEY. Yes, sir.

Chairman HEINZ. Mr. Casey, as you know, Cordis maintains its own pacemaker registry for keeping track of these devices. Has the FDA determined whether there is full accountability in the Cordis registry, and if not, can you give us an example or two where the company's registry was incomplete?

Mr. CASEY. As a routine, whenever we do a medical device inspection, one of the first places we go is to the complaint files and the return pacemaker files, where Cordis routinely tests any returned pacemaker. The reason we do this is because our primary concern, of course, is consumer protection, and we want to identify any trends of failure in any particular model number or any particular device which may impact adversely on the health of the user population.

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[8] See appendix VI, p. 606.

For a number of years, we have been routinely looking at these complaint files, with the belief that they were fully accurate. We learned later, through possibly poor communications on behalf of Cordis, or for whatever reason they may say, that there were complaints in the legal department concerning device failures that were not reported into the complaint file. There were approximately 57 of these complaints in the legal department identified as not being in the normal complaint files.

Chairman HEINZ. Is it also accurate that with respect to the Lambda, Theta, and Stanicor recalls that according to Cordis, there were more than 7,000 of those pacers that were not in the Cordis Miami registry, while over 6,000 of those were distributed in foreign country; nonetheless, 783 of the total were distributed in the United States, and that the reason that they were not in the Cordis registry is because the physicians had not returned the registry forms to the company; is that correct?

Mr. CASEY. That is correct. That is my perception.

Chairman HEINZ. Mr. Spanioli, Cordis states that prior to the April 1985 recall and notice on the Lambda/Theta/Stanicor pacemakers, the company informed physicians of a potential problem in their product updates. In a June 1984 meeting [9] with company officials, however, you and Mr. Casey expressed concern over the product update that was sent to physicians in April 1984.

What was that concern about?

Mr. SPANIOLI. As has just been described, the Lambda pacers had been identified to have a potential printed wiring board failure mechanism that would result potentially in a sudden no-output situation.

The concern that we expressed to the company at that time was that if indeed this was a potential problem, we could not understand why they would not continue to relate the failure mechanism to physicians in their product update letters that they mailed to physicians.

Chairman HEINZ. Mr. Casey, FDA finding No. 22 [10]—and we have given you a copy—states that, quote, "Complaints pertaining to any hazard to safety are not immediately reviewed, evaluated, and investigated, nor are they maintained"—this is by Cordis—in a separate portion of the complaint file.

Could you give us an example or two of this deficiency, and has the company corrected this problem to the satisfaction of the FDA?

Mr. CASEY. Yes, Mr. Chairman; I will be glad to. If you will allow me, I would like to comment on the last item concerning product updates, that was just discussed.

Chairman HEINZ. By all means.

Mr. CASEY. We pointed out to Cordis that even though they had omitted the sudden no-output failure mode from the April 1984 product update, that we certainly did not feel that the product updates were an adequate mechanism to notify physicians of a significant health problem.

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[9] See appendix VI, p. 650.
[10] See appendix VI, p. 603.

In regard to your question concerning complaints, and to give a couple of examples, there was one complaint that concerned a Model 334A pacer that had a rate decrease and also was reported to be a runaway pacer at 160 to 170 pulses per minute. The pacer was explanted on October 18, 1983, and returned to Cordis on November 1, 1983. The pacer was analyzed by Cordis on November 16, 1983, with the conclusion that the pacer failed due to early battery depletion. A health hazard assessment in this instance was not initiated until December 16, 1983, after this particular complaint was brought to the attention of management at Cordis.

Chairman HEINZ. And it was FDA that brought that to Cordis' attention; is that right?

Mr. CASEY. Pardon, sir?

Chairman HEINZ. Did FDA bring that particular situation to Cordis' attention?

Mr. CASEY. Yes; we did.

Chairman HEINZ. Not the other way around.

Mr. CASEY. Correct.

Chairman HEINZ. There are other findings—No. 24 [11]—would you summarize No. 24 for us?

Mr. CASEY. This concerned a pacer-dependent patient who had a failure in her pacer on December 25, 1983. We found out about this, I believe, in February, and even though the sales representative for Cordis had physically picked up that particular pacer after explantation, on December 26, it was not returned to Cordis for testing or evaluation until February 6, 1984.

Chairman HEINZ. So, that is 5 or 6 weeks later, and that pacer failure resulted in cardiac arrest of that patient; is that right?

Mr. CASEY. Yes, sir; I believe that is the case.

Chairman HEINZ. All right. Well, gentlemen, you have been extremely helpful. I think what we have learned here is that it is possible to have many significant problems, as good and necessary as pacemakers can be, should be, and often are for patients, nonetheless, you have documented, I think, the need for a good deal more effort on our part. By effort on our part, I mean your agency, FDA, which is charged by us with maintaining the pacemaker registry. There is no doubt in my mind—I am not going to put you on the spot and ask you what you think on that—but the Commissioner of FDA has testified as to the need for the pacemaker registry and for a number of other improvements as well.

You have given us really a case history of how something can go wrong, and it has been very instructive. I commend you for your professionalism, for your patience, for your painstaking care, not just here but in your everyday work. You, clearly, spent an enormous amount of time trying to get to the bottom of the facts and circumstances regarding this case. You have done it in the interest of protecting the public health, and I think we are all grateful to you. And we particularly appreciate your time and effort here today. You could have been working on something else if you had not been here. But, hopefully, this will make your jobs easier in the future, and make it not only easier but more effective.

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[11] See appendix VI, p. 604.

So, I thank you, all three of you, for being here. Thank you very much.

Chairman HEINZ. Our next witness will be Dr. Weldon of Cordis Corporation.

Dr. Weldon, while you are arranging yourself there, let me say I want to thank you for being here today to share with us your company's response to the findings of the FDA investigation of Cordis that began in December 1983.

May I say that I do not believe that the kinds of problems and deficiencies which the FDA found at Cordis are limited to your company alone; but wherever and whenever these problems exist, they are a matter of grave concern, I suspect to you, but certainly, to us; they have to be addressed, preferably, by internal company management. But if not, then, as everybody understands, it is through the efforts of the appropriate regulatory agencies. And we look forward to learning and understanding how your company has responded to the FDA findings.

Would you please stand and raise your right hand? Do you swear to tell the truth, the whole truth, and nothing but the truth, so help you, God?

Dr. WELDON. I do.

Chairman HEINZ. Thank you.

Let the record show that the witness responded in the affirmative.

Your prepared testimony, Dr. Weldon, has been received and wiil be made a part of the record. In the interest of saving time, however, you certainly can summarize your testimony if you would like to. So, please feel free to proceed as you wish.

STATEMENT OF NORMAN R. WELDON, PH.D., PRESIDENT AND CHIEF EXECUTIVE OFFICER, CORDIS CORP., MIAMI, FL

Dr. WELDON. Yes, sir; In the interest of time, I will summarize that testimony.

As you stated, I am Norman R. Weldon, president of Cordis Corp. With me today are Dr. Patricia Kelsch Woolf and Harold Hershenson. Dr. Woolf is a Cordis director and the chairperson of our Quality Committee. Dr. Woolf is also a member of the faculty of Princeton University with an academic specialty in biomedical ethics. Mr. Hershenson is executive vice president of Cordis Corp. and is the principal quality official of the company.

We are here to comment upon the Cordis response to a long series of FDA investigations, to offer our thoughts on the national pacemaker registry, and to attempt to answer any questions which the committee may have.

I have given your staff the written response, which you acknowledged, and which is too lengthy to present in my allotted time. But let me begin this testimony by assuring you that Cordis shares your interest in advancing the health care of all our citizens. Over the past 26 years, Cordis Corp. has made a series of major technical contributions to medical science. Few companies, regardless of size, can approach our record of continuous, prolific medical achievements.

We are equally proud of our reputation for ethical business and marketing practices. The record clearly shows that Cordis has never compromised ethical standards, even when our policy has cost us customers and market share.

But I suspect that we were invited here not because of our virtues and many accomplishments, but because of two design errors which occurred in 1975 and 1979, which have led to less than optimal performance in certain pacemaker models sold by the company.

In both cases, product performance was adversely affected several years after the date of sale, by factors that were both unknown and unknowable at the time the designs were completed and reviewed.

Unknowable problems will always be a major concern for those of us who use technology to serve the medical needs of our citizens. But I can assure you that we at Cordis place the safety of the public and of patients at the very top of our priority. We employ exceptionally well-qualified scientists, engineers and technicians, and we provide them with the finest tools to do their jobs.

And I can also assure you that all Cordis employees are working as hard and as smart as we know how to produce products of the highest possible quality.

In addition, both senior management and the Cordis board of directors are totally committed to patient safety and product quality.

In addition to our goals and intentions, I am certain that you are interested in some of the actions that we have taken in response to these problems.

First, our board of directors has established a quality committee, authorized to hire its own independent quality auditor, to perform quarterly reviews and to make reports directly to the board of directors. I consider this an innovation which will eventually be adopted by many health care companies.

Second, Cordis has retained two internationally known consultants to help our management team attain world-class quality standards in areas where Cordis has not previously been a leader.

Third, the company has upgraded, restaffed and redocumented two operating areas which were extensively examined by the FDA.

Fourth, with leadership from our board of directors, we are more seriously considering the FDA's perspective in problems, and attempting to resolve all of the outstanding issues cooperatively and not confrontationally.

And fifth, we have launched major corporate and divisional programs to emphasize excellence in every job at every level throughout the company. Our management team has a threefold motivation to do a more effective job.

First, we have a very strong concern for the patients who use our products.

Second, we have a sense of pride that our products must be superior to all others made anywhere in the world.

And third, producing products of the highest possible quality is also consistent with our own economic self-interest.

Next, we would like to briefly share our experience and thoughts about the pacer registry.

Cordis maintains its own pacer registry as a quality safeguard and to comply with medical device legislation. Five people and a moderate amount of computer time are required to follow our share, perhaps 17 percent of the pacers sold in the United States. The information gained from the registry and from the products returned from the field is very important in operating our business.

A national registry would be expensive for U.S. taxpayers, but would be very useful to protect the health of pacer patients.

But we do have two concerns. Even though the Commissioner of the FDA was reticent to say so, a national registry is impossible without adequate staffing and funding, and I am not certain that proper staffing and funding is now available.

Second, two of the objectives of Congress—namely, policing of the manufacturers' warranties and prompt reporting of pacemaker defects—have already been addressed by legislative changes that were made in the interim from the time that the national pacemaker registry was proposed to the present.

In summary, the national pacemaker registry is a good idea, but it might not give as much benefit for the dollars expended as was originally anticipated.

Thank you very much for this opportunity to express our views. We will try to answer any questions you might have.

[The prepared statement of Dr. Weldon follows:]

[The oral testimony resumes on p. 88.]

Norman R. Weldon
President and Chief Executive Officer
Cordis Corporation

Testimony Before
U.S. Senate Special Committee on Aging
Washington, D.C.

May 10, 1985

INTRODUCTION

Mr. Chairman and members of the committee, I am Norman R. Weldon. For the past six years, I have served as President of Cordis Corporation in Miami, Florida. Prior to my association with Cordis, I was active in the early development of hybrid microcircuitry. I worked with a team that designed and manufactured miniature, high-reliability electronic circuits for the medical electronics industry and for other high-technology firms. I am also familiar, indirectly, with many of the issues facing this committee. My wife serves as the volunteer chairman of the Area Agency on Aging Committee of Dade and Monroe Counties, an organization that serves the more than 350,000 elderly in Florida's two southern-most counties.

I am here today at this committee's invitation to discuss two general topics: First, the Company's response to the FDA's inspections and investigation; second, my thoughts and views on the National Pacemaker Registry. Before responding specifically to these issues, I want first to provide committee members some insights into Cordis. Doing so should help place my formal opening remarks, as well as my answers to individual questions, in an appropriate context.

Cordis Corporation was founded in 1959 by Wm. P. Murphy, Jr., M.D, a physician and engineer and the son of one of America's first Nobel laureates in medicine. Throughout its 26-year history, the Company has focused upon the application of innovative technologies to patient care. Cordis was an early participant in both the angiographic and heart pacer industries; today, the Company is one of the top three firms in the world in these two fields. Our annual revenues are approximately $200 million and we employ some 3000 individuals in the U.S. and Europe.

Dr. Murphy and Cordis have been partly or solely responsible for a number of major innovations in medical care. These include the following:

The first angiographic injector	1961
The first physiologically responsive pacer	1962
The leading implantable valve for treating hydrocephalus	1965
The first torque-controllable disposable angiographic catheters	1966
The first hollow fiber kidney dialyzers	1970
The first non-invasively programmable pacers	1972
The first totally implantable neural stimulators	1978
The first microprocessor-controlled dual-chamber pacer	1980

However immodest this observation might appear, I would point out to the committee that few other companies, of whatever size, can match this record. These innovations, individually and collectively, have helped shape the face and character of medicine and health care, resulting in numerous benefits to patients, especially elderly patients, throughout the world. Cordis has been successful because, from the start, its board and management have had both the foresight and the resolve to position the Company for technological leadership. We have invested heavily in research and development--even when doing so clearly was not in the best short-term interest of shareholders. In recent years, for example, spending on R&D has averaged some 13 percent of sales, ranking Cordis at the forefront of the industry and near the top for all U.S. publicly held companies.

I trust that members of this committee appreciate the enormous financial risks posed by such heavy investments in R&D. In fact, in today's medical marketplace, influenced as it is by prospective payment and increased competition, companies simply cannot afford as large a commitment to new product development as in the past. Cordis, in fact, is in the process of cutting back its rate of expenditures to some 10 percent of sales.

Another risk inherent in Cordis' approach is technological. The simple fact is that whenever the state-of-the-art is being advanced in either materials science or electronics, unforeseen problems sometimes occur. Such difficulties should be viewed in perspective, however. In the case of pacers, for example, technical problems may increase risks for some patients, and every reasonable effort must be taken to prevent them. Even so, these same devices provide a far greater number of individuals a far higher quality life than they previously enjoyed. Many pacer patients, in fact, return rapidly to the workforce, making cardiac pacing one of the most medically effective and cost-effective therapies.

Also, according to most medical experts, very few pacer problems pose serious health risks for patients. Most such problems are relatively easy to detect and to deal with. Manufacturers' records indicate which pacers are implanted in which patients. Should a product problem occur, the manufacturer, in cooperation with the FDA, alerts individual physicians and recommends specific actions. More often than not the recommendation calls for increased monitoring of the suspect device. Seldom does a problem result in loss of pacing without warning or, more seriously, runaway rates or extra beats. Moreover, should pacing assistance be completely lost, most patients enjoy sufficient intrinsic heart activity that they are not placed in life-threatening situations. Acknowledging this fact, of course, does not minimize the problem, nor does it lessen the need for vigilance throughout a product's life cycle.

Many companies, including some major competitors, operate under a philosophy that is different from Cordis'—and they do so rather successfully. Their strategy is to minimize technological risks and to maximize marketing muscle. Committee members should consider the question of which of these approaches—technological innovation or marketing aggressiveness—best serves the long-term medical and health-care interests of the American people.

Also, in September 1982, this committee conducted hearings on fraud, waste, and abuse in the pacemaker industry. Much of the testimony concerned abusive marketing practices. As a relative newcomer to Cordis at the time, I was proud of the Company's record. No criticism was directed at Cordis. Expressing a viewpoint shared by many, a leading security analyst wrote at that time, "...at the same time as much of the rest of the pacemaker industry labors under the cloud of a federal investigation into sales practices and pacemaker utilization generally, Cordis is armed with a spotless marketing reputation." I can assure you that the Company continues to both preach and practice adherence to the same ethical marketing and business practices that have guided it during the past 26 years.

CORDIS AND THE FDA

During the early 1970s, Cordis management opposed increased regulation of the medical device industry. In 1974, when certain of Cordis' first generation of programmable pacers failed to achieve their projected reliability, the Company became one of the principal case studies for the passage of the Medical Device Amendments of 1976. Today, led by a new management team, Cordis supports the aims of device regulation and encourages cooperation with the FDA.

Following the long and costly confrontation between Cordis and the FDA in the mid-1970s, a constructive atmosphere prevailed for nearly a decade. During this period Cordis significantly improved its quality systems, regained the confidence of the medical community, and developed a new generation of devices that dramatically improved the quality of life for thousands of elderly persons.

From 1975 until late 1983, the relationship between the FDA and Cordis was, in my opinion, professional and cooperative. Cordis was inspected regularly by the FDA and, starting in April 1982, the agency has been informed regularly of the field performance of our products through semi-annual updates, which are mailed to approximately 15,000 physicians worldwide. FDA inspections, between 1975 and late 1983, were relatively brief and resulted in modest numbers of suggestions for improvements, which Cordis management promptly addressed.

During 1983, with gains from the Company's technologically advanced dual-chamber pacers, Cordis' sales soared. Companies with older technology, and competitors whose integrity had been questioned in hearings before this committee, did less well. During the second half of 1983, however, some Cordis pacer batteries manufactured prior to October 1980 began to exhibit early depletion. The cause of the problem was determined in late November 1983, and the FDA and physicians were notified during the first week of December. Concurrent with the notification, the FDA initiated an inspection of the Company.

During the next four months, the inspection continued in a manner consistent with the detailed, tenacious thoroughness which the public expects, and has a right to expect, from the FDA. But then the tone appeared to change. Part of the reason, undoubtedly, related to receipt by FDA, at approximately that time, of stolen Company internal quality audits and engineering reports. Such reports are a normal and fundamental part of the Company operation, but they are also purposely self-critical. They point out problems, or possible problems, in early stages of design, development and manufacture. It is, in fact, on the basis of such information that companies are able to make refinements, changes, and improvements in subsequent products or subsequent generations of the same product. It is standard industry practice not to share such internal documents with the FDA or with any other regulatory agency. Doing so doubtless would result in the reports becoming less candid, negating their usefulness. It is precisely because engineers and internal auditors feel unconstrained in their freedom to make such observations that the reports make valuable contributions to the production of high-quality medical devices. Nevertheless, what made the reports so damaging in this instance was that the thief apparently presented them in such a way to allege that Cordis management had made decisions inconsistent with protecting public health and safety. These allegations, although totally without merit, resulted in a variety of well-publicized actions and accusations that reflected negatively on the Company and on the orderly functioning of the regulatory process. Several months elapsed before inspections of the Company resumed a constructive focus and manner.

In September 1984, a team of six FDA inspectors began a thorough review of Cordis' manufacturing and engineering documentation, its operating discipline and its practices and procedures. Lasting through November and extremely detailed in its focus, the redirected inspection addressed Cordis' compliance with the FDA's Good Manufacturing Practices. The resultant report outlined several areas that needed management's attention. It also indicated that most problems were confined to two manufacturing units. Other operations were, as they continue to be, in relatively good compliance.

INSPECTION OBSERVATIONS

Typically, a company can expect to receive two criticisms (or observations, in FDA parlance) per inspector for each day worked. For example, if an inspection lasts one man-week, a company can expect ten observations; ten man-weeks, 100 observations, etc. Since December 1983, FDA inspections of Cordis have consumed more than an estimated 50 man-weeks. They also have resulted in 432 observations. I know of no other company that has been as thoroughly reviewed.

One of the FDA's general concerns relates to the Company's adherence to its own specifications. Let me attempt to place this issue in context. As part of its manufacturing practices, and as is common in the electronics industry where I gained my experience, Cordis established stricter specifications for components and work-in-process than was needed for the final products. Known as "guardbanding," the practice is designed to assure that finished products always meet or exceed specifications and to direct management's attention to "near miss" situations. However, because guardbanding standards are more strict, the practice also results in the use of components that earlier had not met the higher guardband specifications. The concept of guardbanding was not anticipated by GMPs and was unfamiliar to FDA inspectors. Consequently it led to needless and totally unjustified criticism of the Company. Nevertheless, to avoid a similar problem in the future, Cordis has changed its practice to conform to regulatory expectations.

I would also like to call the committee's attention to a letter from a Cordis supplier to Mr. John Villforth, director of the FDA's Center for Devices and Radiological Health (Exhibit A). The letter, which was neither solicited nor encouraged by the Company, reads in part, "In our opinion, the Cordis specifications for electronics are the most demanding of any implantable electronics we manufacture... [The Company's reliability requirements] add significantly to unit cost, which over the years, Cordis has been willing to accept to insure that they receive the quality product that they demand."

The so-called charity pacers provide another perspective on the specifications issue. As one of the FDA's regulatory actions, Cordis was required to write letters to monitoring physicians about minor out-of-specification conditions of 30 pacers that the Company had earlier donated for use in indigent patients. This action made it appear that Cordis gave away or, worse yet, sold defective or substandard units--placing, it might appear, a reduced value on the lives and safety of indigent patients. In fact, the devices in question were both safe and effective; they simply did not meet Cordis' own exacting specifications. For example, whereas the Company might specify a rate range of 68-72 beats per minute for a given model pacer, the donated pacer could have been known to function at 67.9 or 72.1 beats per minute. In other instances a donated device might have surpassed its use-before-date yet still offer many years of useful life. In each case, Cordis alerted the physician to the specific out-of-specification or out-of-date condition. To my knowledge, there has not been a single report of a problem associated with any of these charity units. Nevertheless, the Company now conforms to the FDA policy in letter and in spirit: All nonconforming product is destroyed. It might also interest members of this committee that Cordis did not treat the donated units as "charitable contributions" for tax purposes. The Company's only interest was to provided needed help for patients who otherwise might not have received it.

I would also like to emphasize for the record, Cordis' prompt action of informing both customers and the FDA of potential product problems. In the case of Gamma pacers, Cordis voluntarily notified the FDA on December 2, 1983, and physicians on December 5, within days after extensive testing revealed the source of the problem. The Company's first warning on the Lambda/Theta series pacers was issued by way of a Product Update in April 1982, with additional updates to both the FDA and physicians every six months thereafter.

Several additional observations are germane to the Gamma and Lambda/Theta notifications. One is the fact that Lambda and Theta series pacers were introduced to the market in late 1975, almost a decade ago. The first Gamma units were marketed in November 1979. In each instance, the problems that concern us today had their origin in the earliest models of these devices. Moreover, having joined Cordis in mid-1979, I can assure you that considerable progress has been made on virtually every front since then. It is also worth noting that many of the original Lambda units continue to function with high reliability after more than 8 years of service. In fact, overall, Lambda and Theta series pacers have achieved excellent performance relative to longevity and reliability (Exhibit B).

I would also like to call to the attention of members of this committee an important fact concerning Cordis' pacer battery. Even given all past notifications of Gamma units and allowing for continued improvements in battery manufacturing operations, the only ongoing study of industry pacer power sources confirms that Cordis' battery outperforms all other lithium power sources (Exhibit C). In fact, the only power source that surpasses Cordis' lithium battery is the Company's nuclear battery, which is no longer produced. The Company stands totally behind the efficacy and reliability of its lithium battery.

Another of the FDA's concerns was that the Company had made product changes without first securing the agency's approval. The preamble to the 510(k) regulations indicates that a manufacturer is the "person best qualified" to decide which changes could significantly affect the safety or effectiveness of a device and that a 510(k) is not required for "every change in design, material, chemical composition, energy source or manufacturing process...". Also, in the past, FDA officials speaking at trade meetings discouraged the submission of 510(k)s for minor changes. Consequently, and in the absence of definitive guidelines, Cordis has used its best judgment in submitting 510(k)s. Nevertheless, the Company is now taking into account and complying with the more stringent current policy in decisions regarding product changes.

CORDIS RESPONSES

It is important that members of the committee not read into my testimony that I or the Company view the FDA observations as without merit. That clearly is not the case. In fact, many of the observations deal with essential elements of our operations. Moreover, I can state categorically, that in response to these observations the Company has taken, or is in the process of taking, a series of actions designed to implement improvements and to further assure product quality. For example:

The Cordis Board of Directors recently implemented two basic modifications in the management of the Company's product assurance system. First, it has established a standing board committee on quality. Second, the board has authorized the hiring of an independent quality auditor to perform quarterly reviews at both the division and corporate levels. Reporting to the quality committee, that individual will perform a function analogous to that of the independent financial auditor.

Another change involves the appointment of two GMP consultants. One is William W. Hines, Ph.D., a Georgia Institute of Technology professor, who, as a member of an FDA advisory panel, helped write the device GMP's. The other is Bernard T. Loftus, a retired FDA official who helped write the drug GMP's and who was responsible for their interpretation and enforcement. These consultants have been reviewing the Company's operations and acting in an advisory capacity to Cordis management and the board of directors.

The Company also has launched major new corporate and divisional programs in pursuit of excellence. Involving product design and specifications, purchased material, process capability and control, and manufacturing and training, the programs will set the stage for further advances in product quality and reliability. All levels of the Company are involved in one or another of the programs.

The Company's battery operation has been completely redocumented, as reported in specific responses to FDA 483 reports. A Battery Manufacturing Task Force has completed a detailed manufacturing review to assure the implementation of all necessary changes identified by the FDA and by Cordis' outside and inside auditors. In addition, the task force has reviewed every activity, station-by-station, to identify any other opportunities for improvements in the battery manufacturing area.

In the sterilization area, Cordis has engaged the services of an expert in designing, building and validating ethylene oxide sterilization equipment. Although confident that all products have been sterilized effectively, the Company nevertheless has made major policy, practice and equipment changes designed to enhance sterility assurance and to follow the most recent scientific findings concerning sterility control.

An even more important change, perhaps, concerns the ongoing relationship between Cordis and the FDA. It continues to improve. Both sides, it appears to me, are now focused on ensuring that Cordis is optimally positioned to design and produce products of the highest possible quality and safety. For Cordis' part, nothing is more important, managerially or financially, than answering the FDA's immediate concerns and restoring the agency's confidence in the Cordis quality system.

Let me assure members of the committee that we, the Cordis board and management, regret the circumstances which have brought us here today. We care very deeply about our customers and our reputation. We intend to allow nothing to stand in the way of our achieving a still higher level of product quality and reliability. Doing so will serve the best interests of our employees, our customers and the American public.

THE NATIONAL PACEMAKER REGISTRY

Mr. Chairman, I will now focus my attention on the National Pacemaker Registry. As the president of a company that is a major supplier of pacemakers, I currently have available to me four sources of information about the field performance of our products. The first and most important of these is our own pacer registry. The Company attempts to track each pacer sold. We also try to retrieve each device after it is replaced or the patient expires. Based upon our own analysis, we believe that the registry is highly accurate for the first three years of pacer service, very useful from three to five years, and only marginally useful beyond that. The registry provides Cordis an excellent "best case" continuing measure of field performance.

Our second most important source of information relates to in-vitro test samples. Each week the Company randomly selects pacers from production and places them in bottles of salt water kept at body temperature. The pacers are adjusted to a pacing rate of 70 beats per minute and operated continuously until their batteries are depleted. The performance of these pacers is measured and recorded monthly. In addition, physicians return to the Company pacers which have been electively removed for various reasons. We also operate these field returns under identical conditions and measure their performance. These test samples give us an excellent "worst case" continuing measure of field performance. The information becomes progressively more useful as pacer models age and as the sample size is augmented by field return devices. By monitoring both in-vitro and pacer registry data monthly, Cordis management has an accurate representation of the performance of the Company's pacers. I would also point out to members of this committee that both the in-vitro and registry data are made available to the FDA.

A third source of data is the continuing study of pacer performance at six major pacing centers by Bilitch et al. This study was initially funded by the FDA and, in my judgment, represented an excellent investment. Cordis uses the Bilitch data to check against our own registry and to compare the performance of both our pacers and battery system (LiCuS) against those of other manufacturers. (A portion of the most recent Bilitch data appears as Exhibits B and C.)

The fourth source of data is the Stimarec Bulletin published by Dr. Weiti in France. Stimarec provides useful anecdotal information but does not attempt to achieve statistical validity.

Given the above information sources, the National Pacer Registry would replace the Bilitch data and, if a way can be found to encourage hospitals and physicians to cooperate, would offer excellent statistical validity. A well-developed and well-accepted National Registry would become a primary source of data for short-term and medium-term performance. It might also be preferred to the Company's in-vitro test data as a source of long-term performance data.

Cordis Corporation supports the National Pacemaker Registry as provided for in Section 2304 of the Deficit Reduction Act of 1984. However, we have a related concern. The FDA is a very major and very necessary regulatory agency. It must function efficiently and it must keep pace with the demands of both the public and those of us who are constantly applying new technologies to human needs.

As a citizen and a president of a health-care company, I am very concerned about the staffing, funding and work load of FDA. The problem, doubtless, is no less acute for the Health Care Financing Administration, but I personally am not as familiar with that agency as with the FDA. During the past six years, I have seen change after change place greater work loads on the FDA. Some of these changes have come via legislation, i.e., Pre-Market Approval, while others have resulted from congressional oversight and pressure. An example of the latter would be the demand that the FDA now require documentation for minor changes previously made by companies without specific FDA study and review.

Another factor that should be considered is that two of the original and principal motivations behind the National Registry no longer exist. First, a clear Congressional intent was that the registry would police manufacturer's warranties and, as a result, help to reduce medical costs. Two years ago hospitals were not diligent in pursuing warranty credits. However, with the introduction of prospective payment, that situation has significantly changed. Hospitals have almost universally switched from policies of lethargic neglect to determined insistence on receiving warranty credits. The other obvious role envisioned for the registry was to provide an early warning alert on potential problem devices. , The Mandatory Device Reporting requirements accomplish much the same thing. Therefore, to the extent that you as public representatives wanted the registry to police warranties or to provide an early warning alert, other legislation has already accomplished those ends.

In summary, the National Pacemaker Registry is desirable and would be useful. It is also time-consuming and expensive. This committee should understand that a shift in FDA manpower and budget to the National Registry could result in less effective regulation and a reduction in services to the public. If resources are available, charge ahead. But, if not, I respectfully suggest that you consider the opportunity costs of redirecting the already limited resources that the FDA has at its disposal.

Thank you, Mr. Chairman and members of the committee for this opportunity.

EXHIBIT

A

RAYTHEON RAYTHEON COMPANY
MICROWAVE AND POWER TUBE DIVISION

INDUSTRIAL COMPONENTS OPERATION
BOX 8900
465 CENTRE STREET
QUINCY, MA 02169

TEL 617-479-5300
TWX 710-337-0870

March 11, 1985
TBG: 50-85

John C. Villforth, Director
(H F X -1) Center for Devices and Radiological Health
Department of Health & Human Services
Public Health Service Food & Drug Administration
Rockville, Maryland 20857

Dear Mr. Villforth:

Since 1970, the Microelectronics group at Raytheon Company, Quincy Massachusetts, has been involved in suppling hybrid micro circuits for use in inplantable devices; primarily in pacemakers but also for such devices as neurostimulators, defibrilators and bone growth stimulators. We initially were drawn into this business because of our experience with configuration controls and traceability methods in making hi-rel micro circuits for satalite and missile applications. Infifteen years, we have manufactured over 50 thousand circuits for use in in-vivo applications for a dozen different companies.

For the past seven years, one of our customers has been Cordis Corporation of Miami, Florida. Recently I have read considerable negative publicity concerning the reliability of Cordis' product. It may be worthwhile for you to know how we, as a supplier of electronics, view the Cordis Corporation. In our opinion, the Cordis specifications for electronics are the most demanding of any inplantable electronics we manufacture. In addition to the specifications, Cordis has developed the necessary systems and procedures to guarantee compliance to their specifications.

For one example, Cordis was a leader of the "burn-to-zero" concept. Because of our military experience, Raytheon was very familar with PDA (percent defective allowable) requirements but when Cordis came up in the late 1970's with the idea that even a 5% unidentified fall out was more than they would accept and that before accepting any product a vendor had to demonstrate that a production lot must pass accelerated burn-in requirements with "zero" defects, there was question on our part as to whether this requirement could ever be met. In the last four years, all of the Cordis product shipped by Raytheon Company was subject to this burn-to-zero requirement and we now try and sell this concept for other hi-rel military applications.

I must stress that we only supply the electronics to the pacer industry and to Cordis, but I find it difficult to imagine that Cordis would apply such rigorous quality standards on the electronics and not to all of the other components used in their systems. The reliability requirements of the Cordis specifications, like all reliability requirements, add significantly to the unit cost, which over the years, Cordis has been willing to accept, to insure that they receive the quality product that they demand.

If our opinion is of any interest to you and you would like to pursue it, I would be glad to come to Washington to discuss it further with you or your staff.

Very truly yours,

RAYTHEON COMPANY
Industrial Components Operation

Thomas Gillis

Thomas B. Gillis
Operations Manager

EXHIBIT

B

Model Actuarial Survival (40 or More Units)

Model	*Number	12 Months	24 Months	36 Months	48 Months	60 Months	72 Months	84 Months	96 Months	120 Months
Lithium Chemistry										
A-Lithium										
ARCO Div. of INTERMEDICS										
APPS	45 2	97.7%	97.7%	97.7%	97.7%	65.2% 66M				
$LiSOCl_2$	2 18 23	±4.4%	±4.4%	±4.4%	±4.4%	±40.3%				
Arcolith 12	136 2	100%	100%	98.9%	98.9%	96.2%	84.7%	81.7%	81.7%	81.7% 115 M
$LiSOCl_2$	14 59 61			±2.1%	±2.1%	±4.3%	±9.0%	±10.1%	±10.1%	±10.1%
CARDIAC PACEMAKERS										
301	273 62	98.7	96.0%	96.0%	95.9%	95.2%	94.2%	89.1%	89.1%	71.9%
Li	18 4 189	±1.3%	±2.3%	±2.5%	±2.8%	±3.2%	±3.7%	±5.0%	±5.0%	±18.4%
401	47 10	100%	95.9%	92.9%	92.9%	88.0%	82.5%	82.5%	82.5%	72.2% 111M
Li	3 2 30		±5.9%	±9.5%	±9.5%	±12.9%	±15.8%	±15.8%	±15.8%	±22.3%
502	340 38	99.0%	97.7%	95.4%	91.4%	86.1%	80.5%	40.3%	33.9% 106M	
Li	60 4 137	±1.4%	±2.3%	±3.4%	±4.8%	±6.4%	±9.3%	±9.6%	±9.8%	
503	138 90	98.4%	94.2%	89.3%	87.0%	86.7%	82.6%	78.3% 88M		
Li	17 3 88	±3.5%	±4.6%	±6.0%	±7.0%	±7.4%	±8.3%	±9.8%		
504	97 32	98.9%	98.9%	98.9%	98.9%	96.4%	91.4%	86.3% 89M		
Li	6 4 55	±2.3%	±2.3%	±2.3%	±2.3%	±5.2%	±8.4%	±11.3%		
505	884 271	99.0%	98.2%	97.6%	96.3%	95.9%	95.9%	95.9% 88M		
Li	16 6 291	±1.0%	±1.2%	±1.3%	±1.9%	±2.1%	±2.1%	±2.1%		
507	66 36	98.2%	98.2%	98.2%	98.2%	94.8%	88.7%	88.7%		
Li	3 0 36	±3.5%	±3.5%	±3.5%	±3.5%	±7.3%	±11.6%	±11.6%		
522	73 38	98.4%	96.5%	94.1%	91.1% 56M					
Li	4 5 26	±3.0%	±4.8%	±6.6%	±8.7%					
530	174 130	99.4%	99.4%	94.7% 41M						
Li	2 0 33	±1.1%	±1.1%	±9.0%						
605	86 37	100%	100%	100%	100%	100%	100% 80M			
Li	0 0 53									
607	54 18	100%	96.5%	92.3%	92.3%	92.3%	92.3%	92.3% 88M		
Li	2 0 34		±6.7%	±10.2%	±10.2%	±10.2%	±10.2%	±10.2%		
630	50 40	97.7%	97.7%	97.7% 40M						
Li	1 1 8	±4.5%	±4.5%	±4.5%						
CORDIS										
166A7	236 92	99.0%	99.0%	94.0%	92.0%	91.1%	80.2%	67.9%	43.9% 104M	
LiCuS	18 7 118	±1.3%	±1.3%	±3.7%	±4.1%	±4.3%	±4.8%	±5.7%	±38.4%	
190A	881 137	99.4%	98.5%	97.7%	93.3%	89.7%	83.2%	78.0%	72.9% 108M	
LiCuS	66 66 277	±0.7%	±1.2%	±1.4%	±2.8%	±3.3%	±4.2%	±5.1%	±7.1%	
190E	219 71	99.5%	99.5%	98.9%	96.2%	92.8%	86.4%	73.3% 90M		
LiCuS	18 31 99	±0.9%	±0.9%	±1.5%	±2.8%	±4.4%	±7.3%	±17.0%		
190F	246 147	100%	99.5%	99.5%	98.8%	97.9% 85M				
LiCuS	3 1 87		±1.0%	±1.0%	±1.7%	±2.4%				
206A	380 71	100%	97.9%	96.8%	95.2%	94.1%	87.0%			
LiCuS	14 4 111		±2.4%	±2.8%	±3.0%	±4.1%	±7.3%			
208A	43 17	97.6%	97.6%	97.6%	97.6%	97.6%	97.6% 77M			
LiCuS	1 0 25	±4.6%	±4.6%	±4.6%	±4.6%	±4.6%	±4.6%			
217A	110 83	100%	100%	100%	100%	100% 86M				
LiCuS	0 0 47									
221A7	84 43	100%	100%	100%	96.6%	88.4%	83.1% 73M			
LiCuS	0 2 31				±4.7%	±8.8%	±10.9%			
232F**	158 146	100% 22M								
LiCuS	0 0 10									
237A	110 76	100%	100%	100%	100%	97.7%				
LiCuS	1 0 23					±4.5%				
334A	128 76	98.1%	98.1%	87.4%	81.7%	34.9%				
LiCuS	10 5 38	±2.7%	±2.7%	±10.1%	±17.9%	±18.9%				
337A	241 151	99.1%	97.6%	92.4%	47.0% 53M					
LiCuS	20 2 66	±1.2%	±2.4%	±5.7%	±18.6%					
402B	88 81	100%	66.7% 19M							
LiCuS	1 0 6		±41.1%							
415A**	223 184	100%	100%	98.1% 31M						
LiCuS	1 1 37			±3.8%						
DAIG/MEDCOR										
3-70C	80 15	97.6%	97.6%	97.6%	93.6%	84.3%	66.0%	50.3%	50.3%	50.9% 108M
$LiAgCrO_4$	16 0 60	±3.3%	[illegible]	±3.3%	±6.4%	±10.3%	±14.3%	±15.5%	±15.5%	±18.3%
8:1	49 14	100%	93.4%	88.3%	80.0%	68.9%	68.9% 75M			
Li	6 0 29		±8.8%	±12.4%	±15.5%	±21.3%	±21.3%			
EDWARDS										
23 U	83 13	96.6%	96.6%	96.6%	93.1%	77.6%	58.8%	42.8% 77M		
$LiAgCrO_4$	12 0 38	±4.7%	±4.7%	±4.7%	±8.0%	±15.0%	±20.4%	±25.2%		
INTERMEDICS										
223	[illegible] 21	100%	100%	100%	100%	96.7%	78.1%	66.3%	58.6%	29.3% 97M
Li	[illegible] 27					±6.3%	±17.2%	±22.4%	±28.1%	±29.0%
253-01	41 16	94.6%	94.6	81.6%	78.1%	72.1%	61.8% 78M			
Li	9 0 16	±7.1%	±7.1%	±13.4%	±14.4%	±17.2%	±22.5%			
253-02	87 46	100%	100%	100% 42M						
Li	0 0 21									
253-05	109 67	98.9%	98.2%	97.6%	97.0%	92.5% 88M				
Li	5 0 36	±2.2%	±2.2%	±3.4%	±3.4%	±6.5%				
253-07	210 170	100%	100%	100% 34M						
Li	0 0 46									
253-08	43 32	100%	92.9% 29M							
Li	1 0 10		±13.0%							
256-01**	229 117	99.5%	97.9%	91.6%	88.7%	87.0% 62M				
Li	45 6 71	±0.9%	±2.0%	±5.9%	±8.5%	±9.6%				
283-01**	90 46	98.4% 17M								
Li	1 0 3	±6.8%								

Model	*Number	12 Months	24 Months	36 Months	48 Months	60 Months	72 Months	84 Months	96 Months	120 Months
MEDTRONIC										
5972	96:21	100%	100%	100%	100%	100%	93.8%	73.8%	58.9% 98M	
LI	9:0:56						±8.2%	±16.8%	±22.3%	
5973	343:126	100%	100%	99.6%	99.6%	99.6%	96.6%	90.6%	53.2%	53.2% 108M
LI	24:5:188			±0.8%	±0.8%	±0.8%	±2.8%	±5.1%	±21.1%	±21.1%
5984	418:231	100%	100%	100%	100% 50M					
LI	0:0:97									
5985	557:378	99.8%	99.8%	99.5%	98.1%	98.1%	98.1%			
LI	3:3:173	±0.4%	±0.4%	±0.7%	±1.1%	±1.1%	±1.1%			
5989	130:62	100%	100%	100%	100%	100%	88.2%			
LI	1:2:65						±20.2%			
5992**	48:11	100%	100%	96.2%	86.2%	46.9%	32.9%	32.9%		
LI	11:1:25			±7.3%	±14.5%	±22.1%	±21.7%	±21.7%		
5994	46:17	100%	100%	96.2%	96.2%	96.2%	96.2% 70M			
LI	1:1:29			±7.3%	±7.3%	±7.3%	±7.3%			
5995	156:69	100%	100%	99.0%	99.0%	99.0%	96.3% 62M			
LI	2:0:89			±1.9%	±1.9%	±1.9%	±3.6%			
7000**	71:48	100%	100%	100% 40M						
LI	0:3:22									
7000A**	136:101	98.4%	98.4% 31M							
LI	2:1:32	±2.3%	±2.3%							
7006**	85:78	100%	100% 30M							
LI	0:0:7									
8420	85:71	100%	100%	100% 38M						
LI	0:0:14									
8422	123:118	100%	100%	100% 38M						
LI	0:0:15									
8423	280:230	99.6%	99.6%	99.6% 48M						
LI	1:1:48	±0.7%	±0.7%	±0.7%						
PACESETTER										
221	146:75	100%	100%	96.9%	96.9%	96.9%	74.2% 63M			
LI	2:3:66			±2.1%	±2.1%	±2.1%	±26.0%			
281**	40:31	100%	100% 27M							
LI	0:1:8									
SIEMENS-ELEMA										
668	86:69	100%	100%	94.4% 49M						
LI	1:0:15			±10.4%						
TELECTRONICS										
2291**	52:46	100% 18M								
LI	0:0:6									
B-NUCLEAR										
CORDIS										
184A	96:41	100%	100%	96.2%	96.2%	96.2%	94.1%	91.4%	91.4%	91.4% 116M
Pu***	4:0:13			±3.6%	±5.2%	±5.2%	±6.6%	±8.2%	±8.2%	±8.2%

*Number in Series:Still Active
Fail:Elective:General
**These models are dual chamber pulse generators. All others are considered single chamber.

The following pulse generators are no longer reported:

Manufacturer	Model Number	Date of Last Report
Am Tech	DU 300/301	March 1981
ARCO	ARCO 8	March 1984
CPI	901	March 1984
Coratomic	L500	September 1982
Cordis	223D	May 1984
Edwards	21S	September 1983
	21U	March 1984

EXHIBIT

C

CARDIAC PACEMAKER PULSE GENERATORS

Table I.

Overall Actuarial Survival Lithium and Nuclear

	Power Source	Number	12 Months	24 Months	36 Months	48 Months	60 Months	72 Months	84 Months	96 Months	120 Months
	A. *Lithium Chemistry*										
	Iodine	6853	99.1%	98.3%	96.1%	94.4%	92.0%	85.8%	75.6%	67.8%	53.0%
	LiI		±0.3%	±0.4%	±0.6%	±0.8%	±1.1%	±1.9%	±3.1%	±4.4%	±13.5%
	Silver	557	98.6%	98.6%	97.6%	93.2%	73.3%	53.9%	38.8%	37.3%	33.1% 112M
	Chromate		±1.1%	±1.1%	±1.6%	±3.0%	±5.9%	±7.2%	±8.0%	±8.2%	±9.0%
	$LiAgCrO_4$										
	Thionyl	273	99.6%	99.2%	98.0%	92.8%	87.9%	75.2%	49.2%	49.2%	49.2% 118M
	Chloride		±0.7%	±1.1%	±2.0%	±4.2%	±5.8%	±9.3%	±19.0%	±19.0%	±19.0%
	$LiSOCl_2$										
	Lead	56	96.0%	92.7%	66.1%	40.0%	40.0%	40.0%	40.0%	31.1% 100M	
	LiPb		±5.4%	±9.3%	±15.8%	±17.2%	±17.2%	±17.2%	±17.2%	±18.7%	
Cordis	Cupric	2856	99.4%	97.8%	94.5%	90.4%	87.4%	82.3%	77.4%	70.0% 108M	
	Sulfide		±0.3%	±0.7%	±1.1%	±1.6%	±1.9%	±2.5%	±3.5%	±8.0%	
	LiCuS										
	B. *Nuclear*	146	99.3%	98.6%	97.0%	96.1%	96.1%	94.2%	92.0%	90.6%	90.6%
			±1.4%	±2.0%	±3.0%	±3.3%	±3.3%	±4.2%	±5.1%	±5.7%	±5.7%

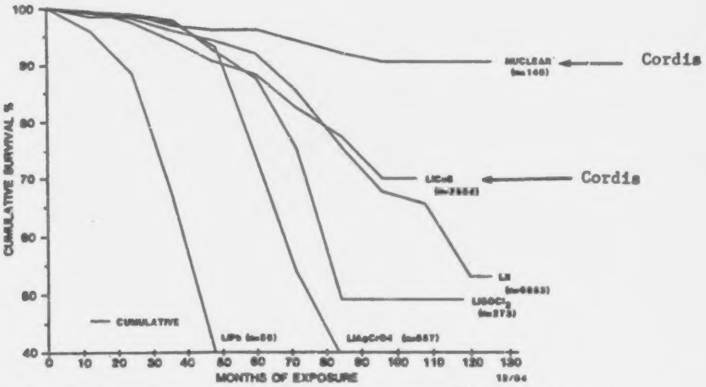

Figure 1. *Overall pulse generator performance by basic power sources. This is a graphic representation of data given in Table 1.*

Chairman HEINZ. Dr. Weldon, I commend you on your very well-prepared statement, both the one you have just given and the one that you provided to the committee.

You stated in your prepared remarks that in response to the FDA investigation, Cordis has taken or is in the process of taking "a series of actions designed to implement improvements and to further assure product quality."

It is obvious from your written responses to FDA that you have made improvements in your operations.

Dr. WELDON. Yes.

Chairman HEINZ. But what specifically are you in the process of accomplishing right now, at this time?

Dr. WELDON. We have made a series of improvements, and we have asked the FDA, I believe on April 15, to come in and check our progress.

We would not have made such a request without already using our outside consultants to ensure that we have met the FDA's concerns. But I will not consider our job finished until we have actually satisfied the two gentlemen that appeared before you earlier today.

Chairman HEINZ. Is there a specific area, though, which you really want to make more improvement in?

Dr. WELDON. The two areas which were of major concern both to myself and our management team, as well as to the FDA, was our battery manufacturing operation and the sterilization facility within the company.

The bulk of the criticisms we received were in those areas, and the majority of our attention in achieving improvements has been focused on those two departments.

Chairman HEINZ. Dr. Weldon, you have stated that since December 1983, the FDA has presented 432 so-called observations concerning the problems and deficiencies in Cordis operations.

Dr. WELDON. Yes.

Chairman HEINZ. First, can you tell us if this number of observations is extraordinary for such an FDA investigation; and second, roughly how many of that 432 do you or your company feel were helpful and justified?

Dr. WELDON. That is a very interesting question. I have been in this job or a similar job for 6 years. For the first 5 years, we received, I would say, from 7 to 15 observations during the inspections that occurred each year.

Chairman HEINZ. So, in that sense, 432 is——

Dr. WELDON. So, in that sense, 432 is a very large number—I do not know of anybody who has ever received 432 observations. It represents an enormous amount of commitment by the FDA and some very competent people that you were talking to, who went through our operation in great detail.

I would say that many of the observations were useful in identifying situations that could be improved. I think that if you try to compare 432 observations at Cordis in 1984 with, say, 20 observations at another company, you would get a very incorrect impression of our company.

The FDA has made a major expenditure of time and effort with Cordis, and that resulted in many criticisms, and a number of these criticisms will help us do a better job for the public.

Chairman HEINZ. You have been through this lengthy compliance investigation by the FDA.

Dr. WELDON. Yes.

Chairman HEINZ. Do you have any criticisms of the process?

Dr. WELDON. There are a few comments that might be useful. The device legislation is properly a very loosely drawn combination of statements. It leaves an enormous amount of interpretation to the FDA, to the company, and to the individual inspectors who are in the field. And I think that is proper. But it can lead to an extended amount of disagreement over issues. So, the process can generate an enormous amount of publicity. And this one certainly has.

But I think the process is basically a viable one, and I would tell you that although the FDA has been in my hair for 17 months, they have extensively looked at our operation, they have made assertions which I do not believe are accurate, they have still done an excellent job of serving the interests of the public, and I wish that all my competitors could have exactly the same advantage that I have had over the past 17 months. [Laughter.]

Chairman HEINZ. It sounds like a version of the old adage, "Aren't you glad you do not get all the government you pay for?"

You mentioned inaccuracies. In that earlier testimony from the FDA investigators, they related the events surrounding the destruction of the Cordis internal audit report on the Gamma battery early depletion problem.

Dr. WELDON. Yes.

Chairman HEINZ. What do you know about that particular event?

Dr. WELDON. Well, that is a perfect case of the FDA answering exactly the question you asked, and perhaps leading the audience to a totally different conclusion than might properly be drawn.

We have a staff of auditors within the company whose job it is to find fault with all the rest of us. And they are routinely assigned the task of going in and playing FDA, only with a great deal more information than the typical FDA investigator has.

Their reports are biting, incisive, very direct, and extremely useful to our management in determining where activity needs to be focused.

It has been the practice of the industry—defended by the FDA, I believe—that these reports should never be made available to the FDA, because making them available to the FDA would mean that the company would have less candor in pursuing useful internal quality auditing activities.

So, over the years, there has been the understanding that these audits would not be seen by the FDA.

To prevent an overzealous and aggressive investigator from receiving them anyway, on advice of counsel, Cordis and, I believe, all the other companies receive the reports, review them extensively and destroy them. And, of course, I would also point out that you said that we lied in response to that testimony, and——

Chairman HEINZ. Well, I said there was another alternative or two.

Dr. WELDON. Yes; when the FDA came into our operation with a copy of that audit, and asked us to supply a copy, we were at a loss to figure out how to do it. We eventually located a draft copy that one of our employees had, I believe in files at his home, and that is how we were able to produce it. And that probably is the reason why FDA personnel had trouble identifying the first document, because I believe they have the only existing copy of the final audit.

Chairman HEINZ. That is the one dated the 23rd, the one we are talking about?

Dr. WELDON. It was dated in the fall of 1983. We had seen some early depletions and were investigating them.

Chairman HEINZ. What is a little confusing to me about the memorandum being at the home of the employee——

Dr. WELDON. I am not certain of that.

Chairman HEINZ [continuing]. Is that they were both dated the same date. Now, we all take memos home, but generally, when you produce a memo and take it home, you produce the revised version a day later. So, it is a little unusual.

Dr. WELDON. I will check the facts of what I have just stated, and if they are inaccurate, I will make a revision and submit it to you.

Chairman HEINZ. According to the FDA investigators, a subordinate of yours——

Dr. WELDON. Excuse me. It is just being pointed out by my counsel that we are confusing two documents here—but let's go ahead.

Chairman HEINZ. All right. According to the FDA investigators, a subordinate of yours apparently stated to them in June of last year that the company would consider adopting a policy of not destroying reports prepared in response to complaints about a specific product. Is that accurate, and if so, has Cordis adopted this policy?

Dr. WELDON. Yes; if you will recall my response to an earlier question, Cordis does not give internal audits to the FDA and does not plan to give internal audits to the FDA.

Chairman HEINZ. Yes.

Dr. WELDON. The FDA stated that their position was that the Battery Department audit was not an internal audit, but was a response to a field problem. If it was a response to a field problem, the FDA has every right to have that document. And I believe that they had a very valid argument in this case. As a result, we agreed to supply the draft document. And in any other case, where we are actually investigating a field problem, I believe that it is appropriate that documents be made available, and they will be made available to the FDA.[1]

Chairman HEINZ. Regarding the FDA investigators' testimony earlier on the altered Cordis memo provided to FDA, what do you know about that particular event, the altered memo, the two-page memo that became a one-page memo?

Dr. WELDON. Mr. Chairman, that is one of the most serious and embarrassing aspects of this entire investigation. I did not know of the substitution of that document until just hours before the FDA was supplied with the true original copy. Although the altering of that document probably in no way impeded the FDA's investigation, it was a severe breach of corporate policy and corporate ethics to have changed that document and left the initial date on it.

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[1] See appendix VI, pp. 564–565.

It has been treated as a very serious matter——

Chairman HEINZ. You may want to—that did not sound quite right. I do not think it sounded the way you meant it, that it was a severe breach of corporate policy to change it and leave the same date on it——

Dr. WELDON. I will just stop before I made the last statement, all right. [Laughter.]

Chairman HEINZ. I do not think you meant that.

Dr. WELDON. No.

Chairman HEINZ. What you meant was it was a severe breach of corporate ethics and policy to create a false document——

Dr. WELDON. Yes, sir.

Chairman HEINZ [continuing]. Irrespective of when or where it may have been dated.

Dr. WELDON. Yes, sir.

Chairman HEINZ. And I appreciate your candor. It reflects very well on you and your company.

In the summer of 1984, the FDA questioned the Cordis decision about dropping from the company's April 1984 product update for physicians the cautionary information concerning the defective Lambda/Theta pacemaker.

Dr. WELDON. Yes, sir.

Chairman HEINZ. We are, of course, aware that Cordis did issue a special recall and notice on those products just last month, but can you tell us what happened with that product update last year?

Dr. WELDON. Yes, sir.

Let me recount a bit. The Lambda/Stanicor/Theta situation goes back to a design problem in 1975. These pacers were sold from 1975 through 1979—virtually all of them. There may have been a few sold in 1980.

The pacer has not performed not as well as we would have liked, but it has performed in accordance with other products sold at the same time in the industry, and we have given you data demonstrating that. So it is not a problem that is a widespread problem with these units.

The units have also met the reliability projections as a part of the labeling of the pacer at the time they were sold. But the nature of this defect was unanticipated, and we felt that it would serve a public interest if we would tell the physicians about the problem, even if we were not required to because of the low failure rate and the conservative labeling of the product. As a result, we began notifying physicians in product updates in April 1982, and we notified them every 6 months thereafter.

When it came time to write the update in April 1984, we felt that the issue had been so extensively covered and was so well-understood in the field that it served no useful purpose to continue repeating it. That was our motivation for not continuing it.

The FDA disagreed with that, and in retrospect, they are right.

There is still a question of whether or not we should have notified on that product last month, but the FDA wanted a notification and we have notified.

Chairman **Heinz**. Well, in retrospect, what you are saying is it sure could not have hurt.

Dr. **Weldon**. That is correct.

Chairman **Heinz**. And on these things, I suppose the lesson is it is far better to be more complete than less complete.

Dr. **Weldon**. And it is far better to err on the side of conservatism.

Chairman **Heinz**. One of the FDA's major findings was that the Cordis evaluation and investigation of complaints pertaining to hazards to safety was slow and inadequate. How has Cordis reacted to those findings?

Dr. **Weldon**. The specific case that was mentioned to you, and there are other similar cases, is where the nature of the initial examination indicates that the product is part of an overall generic problem which has already been identified to physicians.

We put our priority for failure investigation on issues that look different, something that may be an aberration that we do not already know about. Consequently, what our people did was to place more emphasis on some situations than others. The Gamma battery problem was so well-known, and it had happened often enough, that those investigations were accorded a lower priority and were not worked on as promptly.

So the FDA statements are absolutely accurate. But with respect to the speed with which we investigate new and significant things, I do not believe it is representative of our position.

Chairman **Heinz**. Have you made any improvements, though, in your methods of documentation of complaints?

Dr. **Weldon**. Yes, sir. We have improved our methods of documentation in our complaint files. Some of our documentation in the past has been a bit cryptic, understandable only to an electronic technician who may have performed the operation several times. We have expanded the nature and completeness of that data and have also incorporated any of the data that might have been received by the Legal Department, which we had not always done previously.

Chairman **Heinz**. FDA documents indicate that Cordis recently completed an audit and analysis of its improved pacemaker battery manufacturing operations. Is the company willing to share with the FDA the audit report and other internal documents pertaining to this study, or are they really covered by your internal audit policy and that which you say the FDA encourages, which is not to share such internal audit reports?

Dr. **Weldon**. Yes, sir, our recent battery audits do fall in that category. I think it is improper for us to share such audits. I believe it is more appropriate that the FDA comes in and looks for themselves. And we have invited them to do that.

Chairman **Heinz**. I want to thank you for going through a lengthy list of questions. I think you have been extraordinarily candid. When you have found a fault, you have admitted it. That really is to be commended. I wish all of us in politics were as candid as that all of the time.

Dr. **Weldon**. It gets me in trouble sometimes.

Chairman **Heinz**. Well, there is an old Chinese proverb that goes something like that. But let me just ask you one more question having nothing much to do with Cordis, you will be pleased to know—which is, despite your misgivings about the registry, the national pacemaker registry, you nonetheless conclude that it is desirable and useful.

Dr. **Weldon**. Yes, sir.

Chairman **Heinz**. What do you base that conclusion—even though it is the one I am delighted to have—what is your justification for that conclusion?

Dr. **Weldon**. I base my recommendation on the utility of our own registry in assessing the quality of our product, and the usefulness of the nonprofit study—which was initially funded by the FDA several years ago and which was referred to earlier in the testimony—by Dr. Bilitch and other physicians. That limited registry, was an excellent investment for the U.S. public and has served the industry very well.

There are some sticky problems, and you have mentioned one of them in talking with the FDA people. A certain percentage of physicians and hospitals simply will not supply the data——

Chairman **Heinz**. They can't write.

Dr. **Weldon**. I did not say that, sir. They do not see that it is important, and they do not see that it is their business to take that time.

I would also point out that about 30 percent of the initial data we receive for our registry turns out to be erroneous, and a large part of the effort of the people who manage our registry is consumed in following up and calling the hospitals to get the correct data.

Chairman **Heinz**. One of our panelists, Mr. Bysshe, who accompanied Mr. Bliss, recommended—and Dr. Phibbs concurred; although he is not a manufacturer, but he is a user of pacemakers—that it might be a good idea to have a label, a duplicate label, setting forth what was being implanted, the number, the serial number, the type, the one- or two-chamber model, and so forth.

Is that a feasible, practical, good idea?

Dr. **Weldon**. It is a feasible idea. In fact, we are about ready to implement such a system. Some of our competitors use it at the present time. But it includes only a fraction of the data that is necessary for the registry. Nevertheless, that part of the data is best supplied by the method that he described, yes.

Chairman **Heinz**. And it could be made machine-readable——

Dr. **Weldon**. Absolutely.

Chairman **Heinz** [continuing]. As well as human-readable?

Dr. **Weldon**. Absolutely, yes.

Chairman **Heinz**. Very well.

I want to thank you, Dr. Weldon, for really being an excellent witness. You have done very well, I think. You have answered a lot of tough questions. You have answered them honestly and well, and that is all that we can ever ask of a witness.

We thank you very much, and we appreciate your time and attention.

Dr. **Weldon**. Thank you.

Chairman **Heinz**. Would Mr. Zimmerman and Mr. Stollhans please come forward?

Gentlemen, you are respectively, Mr. Zimmerman, you are Associate Director of the Human Resources Division of the General Accounting Office. Mr. Stollhans, you are Assistant Chief of the White Collar Crime Division of the FBI. Do not look at me with such a beady eye. I have got a white shirt on today. [Laughter.]

We want to thank you for appearing here with us today. Following this Committee's 1982 hearing on pacemakers, I asked the GAO, Mr. Zimmerman—and welcome back; nice to see you again—to look into the effect on Medicare of the cost of pacemaker manufacturers' warranty and marketing policies, and hospitals' procedures for acquiring pacemakers. That review is concluded, and we are releasing the GAO report today.

I wish to thank the Comptroller General, Mr. Zimmerman, yourself, and everyone else who contributed to that valuable report. And you will tell us, I understand, of your findings.

Mr. Stollhans will tell us of the FBI's activities with regard to the prosecution and investigation of the illegal pacemaker kickback schemes, a matter of continuing concern to the committee.

Gentlemen, would you mind rising while I administer the oath?

Do you swear or affirm to tell the truth, the whole truth, and nothing but the truth, so help you, God?

Mr. **Zimmerman**. Yes.

Mr. **Stollhans**. Yes, sir.

Chairman **Heinz**. Thank you. Let the record show that both witnesses responded in the affirmative.

Mr. Stollhans, would you please be our first witness, and I would appreciate anything you can do to summarize your testimony.

Please proceed.

STATEMENT OF WILLIAM STOLLHANS, WASHINGTON, DC, ASSISTANT CHIEF, WHITE COLLAR CRIME DIVISION, FBI

Mr. **Stollhans**. Mr. Chairman, I am pleased to appear today to discuss the FBI's experience in uncovering fraud and kickbacks in the cardiac pacemaker industry.

In January 1982, the U.S. Department of Health and Human Services, Office of Inspector General, informed the FBI of allegations that pacemaker manufacturers were paying kickbacks to physicians as inducements to use their products. Such payments violate title 42, United States Code, section 1395nn(b), which concerns Medicare.

As a result, the FBI initiated an investigation of Pacesetter Systems, Inc., of Sylmar, CA, which is known as PSI, based on information that PSI paid physicians kickbacks disguised as rebates, consulting fees, free use of ancillary equipment, and in one case, a kickback was recorded as a loan to a doctor.

Payments were reportedly made for each PSI pacemaker implanted. Regarding the consulting fees, PSI told physicians that they would be paid to evaluate the performance of the PSI pacemakers. However, our investigation disclosed that, in most cases, PSI did not send the evaluation forms to the physicians. In those instances in which the evaluation forms were provided and returned to PSI, the investigation disclosed they were not utilized by PSI.

On December 12, 1983, an indictment was returned by the Federal Grand Jury for the Central District of California at Los Angeles, charging PSI with four kickback counts and one count of conspiracy.

In addition, Ronald Tracy Schaefer, the former president of PSI, was indicted for 20 counts of paying kickbacks, 20 counts of aiding and abetting, and one count of conspiracy. Jason Allen Sholder, a vice president of PSI, was indicted on two kickback counts, two counts of aiding and abetting, and one count of conspiracy. Barry Lester Forwand, the PSI Northeast Regional Sales Manager, was indicted on one kickback count, one count of aiding and abetting, and on one count of conspiracy.

The indictment charged that PSI paid $166,246 in kickbacks between February 1979 and December 1982.

On December 28, 1983, the corporation plead guilty to the four kickback counts. On January 3, 1984, Ronald Schaefer entered a plea of nolo contendere to the one count of conspiracy and 19 kickback counts. At the same time, Barry Forwand plead guilty to one kickback count. Jason Sholder plead guilty to conspiracy on January 4, 1984.

Subsequent to the pleas, on February 6, 1984, PSI was fined $60,000; Ronald Schaefer was sentenced to 3 years probation and a $40,000 fine; Jason Sholder was sentenced to 3 years probation and a $2,500 fine; and was ordered to do 250 hours of community service work. On March 26, 1984, Barry Forwand was sentenced to 3 years probation and fined $5,000.

A second investigation resulting from the original information was conducted jointly by the FBI and HHS, Office of Inspector General. In that case, Telectronics Proprietary, Ltd., known as TPL, a pacemaker manufacturer and distributor located in Englewood, CO, was charged with paying kickbacks to physicians to use their pacemakers. These kickbacks were paid between August 1979 and January 1982.

On July 6, 1984, an information was filed in the U.S. District Court for the District of Colorado, charging TPL with four kickback counts. The information charged that TPL paid a physician over $134,000 in kickbacks. Initially, TPL reportedly paid $250 per implant; however, the kickback was later increased to $400 per implant.

TPL was also charged with giving free use of leased eouipment and accessories valued at $9,065.51 to another physician to induce him to use TPL's pacemakers.

On July 8, 1984, TPL plead guilty to the information, and on August 6, 1984, was ordered to make restitution of $243,115 to the Medicare Program and pay a fine of $50,000.

Additional FBI investigations are underway at this time. Although I am unable to discuss the specifics of these ongoing investigations, I can comment in general terms regarding the schemes that were employed and the timeframes of those activities.

In one instance, a pacemaker manufacturer provided free equipment to hospitals, clinics, and physicians who were high-volume purchasers of its pacemakers. Our investigation has revealed that this policy was continued through February 1984.

In another instance, we have developed information that a pacemaker manufacturing company offered physicians gifts and expense-paid vacations under the guise of having them attend seminars relating to pacemakers. The evidence indicates that these policies were discontinued in 1982.

The evidence developed in these investigations is being evaluated by the Department of Justice to determine if the acts violate the payment of remuneration statute.

This concludes my prepared testimony. I would be happy to answer any questions.

Chairman Heinz. Mr. Stollhans, thank you very much.

Mr. Zimmerman.

STATEMENT OF MICHAEL ZIMMERMAN, WASHINGTON, DC, ASSOCIATE DIRECTOR, HUMAN RESOURCES DIVISION, GAO, ACCOMPANIED BY ED STROPKO

Mr. Zimmerman. Thank you, Senator.

Let me begin first by introducing Mr. Ed Stropko. He is with me today, and he is a new addition to our staff, working in the Medicare area.

Chairman Heinz. Mr. Stropko, welcome.

Mr. Zimmerman. We are pleased to be here today to discuss our recent report concerning pacemaker surgeries. Under Medicare's former cost reimbursement system, hospitals had little incentive to seek the lowest possible price for pacemakers, because Medicare paid them their actual cost of purchasing pacemakers.

However, with the introduction of PPS's fixed payments, improved hospital procurement practices now translate directly into a better bottom line. Hospital administrators are not likely to miss this point because the pacemaker itself is often the single most costly item for patients receiving pacemaker surgery.

Before PPS, hospitals often were not using economical purchasing practices for pacemakers. Although manfacturers offered discounts ranging from 5 to 60 percent, depending on the quantity and type of pacemakers purchased, only 3 of the 12 hospitals we reviewed had obtained discounts during the cost reporting period ending in fiscal year 1981, the reporting period used by HHS to compute the prospective payment rates.

Also, information we obtained from manufacturers showed that on the average, discounts amounted to less than 1 percent of their total sales.

Our report discusses two ways hospitals can enhance their ability to obtain lower pacemaker prices. Hospitals can coordinate pacemaker purchasing by getting physicians practicing at a hospital to agree to use specified types of pacemakers, or they can consolidate purchasing by combining their pacemaker needs with those of other hospitals. Very few hospitals in our sample, including five of the six hospitals owned by chains, were doing this.

We also found that in over half of the cases reviewed, hospitals did not return explanted pacemakers to manufacturers for testing, which was a universal condition for obtaining a warranty credit. Thus, in such cases, obtaining a warranty credit was precluded.

We believe that the lack of incentives under the cost reimbursement system to seek warranty credits, combined with the manufacturers' marketing policies that discourage seeking these credits contributed to hospitals not taking full advantage of the benefits available under the warranties. Also, two major manufacturers that did not offer warranty credits in 1981 now do. Therefore, hospitals should now be seeking and obtaining more warranty credits, and for this reason, we believe unnecessary costs are included in the cost data HHS uses to compute prospective payment rates for pacemaker replacement surgeries.

HHS has the authority to require hospitals to return all explanted pacemakers to the manufacturers and to require the manufacturers to test all returned pacemakers and report the results. In our report, we recommended that HHS use these authorities to obtain the information necessary to assure that Medicare benefits from warranty credits when they are issued. HHS could also use the provisions of this law to gain benefit from warranty credits by deducting the amount of warranty credit from DRG payments. Because it appears that a few credits were obtained during the base year used for establishing the payment rates, such action will not severely affect the fairness of Medicare payments to hospitals.

An additional benefit from implementing our recommendation is that all explanted pacemakers would be tested, which in turn would continue to improve quality of care by better assuring that problems that cause pacemaker failures are identified and corrected.

We also compared the hardware warranty provisions provided in the United States and overseas. In most cases, the warranties were comparable. However, a significant difference in one manufacturer's overseas warranty provisions was that the manufacturer offered a money-back guarantee instead of the replacement-in-kind policy offered by manufacturers in the United States. In the U.S. market, manufacturers' warranties typically require that the pacemaker be replaced by one made by the same manufacturer, which limits somewhat the warranty claims. And I can certainly understand concern on the part of patients and physicians, given some of the cases that were discussed earlier today, their unwillingness to accept a pacemaker that was manufactured by the same company whose pacemaker failed in their case.

Our understanding is that overseas physician communities or paying authorities thought it unethical to require anyone to use a pacemaker manufactured by the same company whose pacemaker had failed. At the time of our visit in late 1983, a number of European companies were in the process of issuing regulations requiring companies to provide money-back warranties. France already requires that all pacemakers be warranted for 4 years and that money-back guarantees be provided.

We also found that a large portion of pacemaker replacements involved pacemakers that are later found to function within the manufacturer's specifications, and thus Medicare may be making unnecessary expenditures. Three manufacturers provided us with data on over 10,000 returned pacemakers, which showed that about 70 percent of them were operating within specifications.

Although changes in patients' medical conditions can necessitate replacing a properly operating pacemaker, industry sources point out a number of other factors that may account for the high ratio of replaced pacemakers that are found to be within specifications.

We believe it is necessary for HHS to review the situations resulting in the replacement of properly functioning pacemakers and take action to minimize unnecessary replacements and unnecessary stress on the patients and their families, and we recommend that HHS do this.

We also assessed the data HHS used to compute the payment rates and identified a number of problems, some of which indicate that the rates may be too high, and others indicate that the rates may be too low.

In our conclusion, our review showed that the data used to compute the cardiac surgery payment rates contained errors that could affect the rates' reasonableness, the data was collected at a time when hospitals had little incentive to take full advantage of purchasing efficiencies and warranty benefits offered by manufacturers, and the data does not reflect the more recent shift toward use of higher cost, more technologically advanced pacemakers.

Because of these factors, we believe HHS should use more current data to reevaluate the reasonableness of prospective payments for pacemaker surgeries.

That concludes my statement, Mr. Chairman. We would be glad to answer any questions you may have.

Chairman HEINZ. Mr. Zimmerman, thank you very much.

[The oral testimony resumes on p. 117.]

[The prepared statement of Mr. Zimmerman follows:]

United States General Accounting Office

Washington, D.C.

FOR RELEASE ON DELIVERY
Expected at 9:30 AM. EDT
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STATEMENT OF

MICHAEL ZIMMERMAN, ASSOCIATE DIRECTOR

HUMAN RESOURCES DIVISION

BEFORE THE

SPECIAL COMMITTEE ON AGING

UNITED STATES SENATE

ON

MEDICARE PAYMENT RATES FOR PACEMAKER SURGERIES

Mr. Chairman and members of the Committee:

We are pleased to be here today to discuss the report we prepared for the Committee entitled Medicare's Policies and Prospective Payment Rates for Cardiac Pacemaker Surgeries Need Review and Revision (GAO/HRD-85-39, Feb. 26, 1985). In preparing the report we reviewed four major manufacturers who account for about 80 percent of domestic pacemaker sales. We also gathered data on all pacemaker surgeries performed at 12 selected hospitals and compared these data to the data used by the Department of Health and Human Services' (HHS') Health Care Financing Administration to establish Medicare's hospital prospective payment rates for pacemaker surgery.

Our review showed that the data used to compute the cardiac surgery payment rates (1) contained errors that could affect the rates' reasonableness; (2) were collected at a time when hospitals had little incentive to take full advantage of purchasing efficiencies or warranty benefits offered by pacemaker manufacturers; and (3) do not reflect the more recent shift toward the use of higher cost, more technologically advanced pacemakers.

Because of the inaccuracies in the data base, stronger hospital incentives for economical procurement of pacemakers to reduce hospital costs, and the shift to more expensive pacemakers, we believe HHS should use current data to reevaluate the reasonableness of prospective payment rates for pacemaker surgeries.

In fiscal year 1984 Medicare paid about $42 billion to the approximately 6,000 hospitals that participate in the program. We estimate that expenditures for inpatient hospital services for pacemaker surgeries under Medicare in fiscal year 1984 amounted to about $775 million, of which about $400 million represented hospital payments to manufacturers for pacemakers.

You asked that my statement concentrate on issues dealing with (1) hospital purchasing practices for pacemakers, (2) pacemaker warranties, (3) removal of working pacemakers, and (4) problems with the data used to set Medicare's prospective payment rates for pacemaker surgeries. I will address each of these issues. I have included as an enclosure to my statement a copy of the digest of our February report which summarizes all of the issues contained in the report.

HOW HAVE INCENTIVES FOR ECONOMICAL PURCHASING BY HOSPITALS CHANGED UNDER MEDICARE'S PROSPECTIVE PAYMENT SYSTEM?

Under Medicare's former cost reimbursement system, hospitals had little incentive to seek the lowest possible prices for pacemakers because Medicare paid them their actual cost of purchasing pacemakers. However, with the introduction of Medicare's prospective payment system (PPS), hospitals now have a much stronger incentive to obtain pacemakers at as low a price as possible. This results because, under PPS, hospitals receive a flat, predetermined payment[1] for each pacemaker surgery and profit or lose depending on whether their costs are below the prospective payment rate. Therefore, hospitals should seek to hold down their costs by obtaining pacemakers as cheaply as possible. This is especially true for pacemaker surgery patients because the pacemaker itself is often the largest single cost item for such patients.

We found that before PPS, hospitals often were not using economical purchasing practices for pacemakers. Although manufacturers offered discounts ranging from 5 to 60 percent depending on the quantity and type of pacemaker purchased, only 3 of the 12 hospitals had obtained discounts during their cost reporting periods ended in fiscal year 1981, the period HHS used to compute the prospective payment rates. Seven of the other nine hospitals could have obtained, but did not obtain, discounts based on the discount availability data we obtained.

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[1] When fully implemented all hospitals will receive the same amount, adjusted to account for differences in wage levels among areas around the country, for urban or rural location, and for whether a hospital is a teaching facility. Currently, rates also differ by census region.

Information we obtained from the manufacturers also showed that relatively few hospitals obtained discounts. Sales where discounts were granted represented 0.5 percent of total domestic sales for one manufacturer and 0.7 percent for another, and 1.2 percent of total revenues for a third manufacturer.

Our report also discusses two ways hospitals can enhance their ability to obtain lower pacemaker prices. First, hospitals can coordinate pacemaker purchasing by getting physicians practicing at a hospital to agree to use specified types of pacemakers. This results in more units of the specified pacemakers being used and, thus, can lead to larger discounts. Only 1 of the 12 hospitals we reviewed coordinated pacemaker use.

Second, hospitals can consolidate purchasing by combining their pacemaker needs with those of other hospitals associated with them through common ownership or control or through a group purchasing arrangement. Again, consolidation increases the quantity purchased and thereby enhances the ability to obtain discounts. Only one of the six hospitals reviewed that belonged to chains obtained pacemakers through consolidated purchasing.

Also, only one hospital obtained discounts for some pacemakers by using a group purchasing organization.

Because hospitals normally were not seeking discounts, the data HHS used to compute prospective payment rates for pacemaker surgeries reflected higher than necessary costs. Introduction of PPS gave hospitals incentives to be more prudent purchasers--and they have opportunities to do so. This should result in a reduction in hospitals' cost of purchasing pacemakers compared to those reflected in the prospective payment rates. We recommended that HHS use data that reflect the improved efficiency that should result from PPS' incentives toward more prudent purchasing when it updates prospective payment rates for pacemaker surgeries.

Did Hospitals Maximize the Use of Warranties for Failed Pacemakers?

Medicare's former cost reimbursement system also gave hospitals little incentive to seek warranty credits for failed pacemakers because they were paid their costs whether or not a credit was received. In fact, obtaining a credit only resulted in a lower Medicare payment to the hospital. However, under PPS, hospitals have a strong incentive to seek warranty credits as a way of keeping costs below the flat prospective payment that is not reduced when credits are obtained.

We found that, in 53 percent of the cases reviewed, hospitals did not return explanted (surgically removed) pacemakers to the manufacturers for testing, which was a universal condition for obtaining a warranty credit. Thus, in such cases obtaining a warranty credit was precluded.

We identified several reasons why explanted pacemakers might not be returned to the manufacturer. First, explanted pacemakers must be replaced by a model made by the same manufacturer in order to obtain a warranty credit. We found that 36 percent of the explanted pacemakers not returned to the manufacturer by the 12 hospitals were replaced by a model from a different manufacturer. Second, none of the 12 hospitals had established procedures to assure that pacemakers were returned. Third, manufacturers reduced sales representatives' or distributors' sales commissions when a warranty credit was issued, thus discouraging the salesperson from providing for the return of explanted pacemakers. Fourth, manufacturers had marketing programs that encouraged replacement of competitors' pacemakers with their own, thus precluding a warranty credit.

We believe that the lack of incentives under the cost reimbursement system to seek warranty credits combined with manufacturers' marketing policies that discouraged seeking warranty credits contributed to hospitals not taking full advantage of the benefits available under warranties. Also, two major manufacturers that did not offer warranties in 1981, the base period used to set prospective payment rates, now do. Therefore, hospitals should now be seeking and obtaining more warranty credits, and we believe unnecessary costs are included in the data HHS used to compute prospective payment rates for pacemaker replacement surgeries.

The Deficit Reduction Act of 1984 gave HHS discretionary authority to require hospitals to return all explanted pacemakers to the manufacturers and to require the manufacturer to test all returned pacemakers and report the results. We recommended that HHS use these authorities to obtain the information necessary to assure that Medicare benefits from warranty credits when they are issued. An additional benefit from implementing our recommendation is that all explanted pacemakers would be tested, which in turn would continue to improve quality of care by better assuring that problems that cause pacemaker failure are identified and corrected.

WHAT ARE THE TYPES AND CONDITIONS OF WARRANTIES?

Manufacturers have offered two basic types of warranties. First, some manufacturers have offered a product or hardware warranty. Such a warranty provides a credit for pacemakers that fail to operate within specifications during the warranty period, usually in the amount of the original cost of the replaced unit or the cost of a functionally comparable unit. Typically, these warranties require that the pacemaker be replaced by one made by the same manufacturer and require that the explanted unit be returned to the manufacturer to verify that it has malfunctioned.

Second, some manufacturers have offered a coinsurance warranty. Such a warranty covers the unreimbursed medical expenses of the patient; that is, those expenses not covered by Medicare or other insurance. Some companies have offered both hardware and coinsurance warranties.

We compared the hardware warranty provisions provided in the United States and overseas. In most cases the warranties were comparable except that two manufacturers offered warranties overseas, but offered no warranties in the United States until 1984.

A significant difference in one manufacturer's overseas warranty provisions was that the manufacturer offered a "money-back" guarantee instead of the "replacement-in-kind" policy offered by manufacturers in the United States. Our understanding is that physician communities or paying authorities thought it unethical to require anyone to use a pacemaker manufactured by the same company whose pacemaker had failed. At the time of our visit in late 1983, a number of European countries were promulgating regulations requiring companies to provide money-back warranties. France already required that all pacemakers be warranted for 4 years and that money-back guarantees be provided.

WHAT WAS THE TESTING EXPERIENCE OF MANUFACTURERS FOR EXPLANTED PACEMAKERS AND WHAT DOES THIS IMPLY FOR MEDICARE?

We found that, because a large proportion of pacemaker replacements involve pacemakers that are later found to function within the manufacturers' specifications, Medicare may be making unnecessary expenditures. Three manufacturers provided us data on over 10,000 returned pacemakers which showed that about 70 percent of them were operating within specifications. Although changes in patients' medical condition can necessitate replacing a properly operating pacemaker, industry sources point out a number of other factors that may account for the high ratio of replaced pacemakers that are found to be within specifications. These factors, which are detailed in our report, include such things as marketing policies that provided for incentive payments for pacemaker replacement and inconsistencies between the standards used by physicians evaluating a pacemaker and the standard used by the manufacturer in factory testing.

We recommended that HHS review the situations resulting in the replacement of properly functioning pacemakers and act to minimize unnecessary replacements. The information that would be obtained by implementing our recommendation, mentioned before, to use the authorities provided by the Deficit Reduction Act of 1984, would help provide the data necessary for such a review.

HOW ACCURATE WERE THE DATA HHS USED TO COMPUTE PROSPECTIVE PAYMENT RATES FOR PACEMAKER SURGERIES?

We reviewed the 1,063 pacemaker surgeries performed at the 12 hospitals during their cost reporting years ended in 1981. Of these, 94 cases were included in the MEDPAR data file[2] HHS used to compute the prospective payment rates. Our comparison of the MEDPAR and cost data HHS used to the data we obtained showed many problems with the HHS data.

First, HHS used unaudited cost reports. We compared the unaudited and audited cost reports for 8 of the 12 hospitals, and the audited reports showed significantly lower costs. For ancillary service costs such as medical supplies and laboratory services, which represent most costs for pacemaker surgeries, the audited costs for these hospitals averaged about 5 percent lower than the unaudited costs. Thus, the use of unaudited cost reports tended to overstate the prospective payment rates.

In addition, about 10 percent of the MEDPAR pacemaker cases were classified in the wrong diagnosis related group (DRG).[3] Eight replacement cases were classified as initial implants, and one initial implant was classified as a replacement. Because initial implants are more costly than replacements, including replacements with initial implants would tend to understate the costs of initial implants, while including initial implants with replacements would tend to overstate the cost of replacements.

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[2] The Medicare Provider Analysis and Review (MEDPAR) file is a 20-percent sample of Medicare hospital discharges which includes information on patients' diagnoses and the hospital charges for services provided.

[3] Each DRG contains diagnoses that are expected to be closely related in the extent of resources devoted to treating patients, and separate payments are calculated for each DRG.

Another 37 pacemaker cases, or about 40 percent, were erroneously classified under DRGs other than pacemaker DRGs. Of the 37 cases, 31 were classified erroneously in lower valued DRGs, which would tend to overstate the costs for these DRGs.

Furthermore, the process used to develop costs for computing the prospective payment rates resulted in inaccuracies because of hospital billing errors and placement of charges and costs in the wrong accounts. These problems could result in either overstatement or understatement of costs depending on the specific facts in each case.

Although we could not assess the precise impact on DRG payment rates of the problems we identified, it is clear that better data are needed to update DRG payment rates. These errors affected not only the pacemaker DRGs but others as well.

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This concludes my prepared statement. We will be happy to address any questions you may have.

COMPTROLLER GENERAL'S
REPORT TO THE SPECIAL
COMMITTEE ON AGING
UNITED STATES SENATE

MEDICARE'S POLICIES AND PROSPECTIVE PAYMENT RATES FOR CARDIAC PACEMAKER SURGERIES NEED REVIEW AND REVISION

DIGEST

Pacemaker industry sources estimate that over 100,000 pacemaker surgeries were done in 1984 and that about 85 percent of the patients receiving pacemakers were eligible for Medicare. GAO estimates that in 1984 Medicare paid about $775 million to hospitals for pacemaker surgeries, of which about $400 million represented hospital payments for pacemakers.

As a follow-up to a September 1982 hearing, the Chairman, Senate Special Committee on Aging, asked GAO to review a number of issues related to the effect on Medicare costs of certain pacemaker industry practices. In response, GAO reviewed the effect on Medicare costs of

--pacemaker manufacturers' warranty policies,

--manufacturers' marketing policies, and

--hospitals' procedures for acquiring pacemakers and charging for them.

When the Congress enacted a prospective payment system for Medicare hospital services in April 1983, GAO's work was expanded to include an analysis of the impact of manufacturers' and hospitals' policies on the reasonableness of Medicare's new payment rates for pacemaker surgeries.

The prospective payment system classifies cases into diagnosis related groups (DRGs), each of which covers a set of diagnoses expected to require similar levels of hospital resources for treatment. Each case falling under a DRG receives the same predetermined payment rate. There are four pacemaker DRGs. All DRG payment rates were calculated from 1981 cost report data provided to the government by over 5,000 hospitals and from data on a 20-percent sample of 1981 Medicare discharges. The Department of Health and Human Services (HHS) is required to update the prospective payment rates annually and reevaluate the DRGs at least every 4 years. (See p. 3.)

GAO obtained information about warranties and marketing and pricing policies from the four pacemaker manufacturers that account for about 80 percent of sales in the United States. GAO also obtained data on 1,063 pacemaker surgeries performed at 12 hospitals during their cost reporting years ended in fiscal year 1981, the period represented by the data used by HHS' Health Care Financing Administration to compute Medicare's prospective payment rates. The hospitals were judgmentally selected to provide a mix of the types of hospitals doing pacemaker surgeries and to obtain data on the four manufacturers.

PROSPECTIVE PAYMENT SYSTEM INCENTIVES SHOULD LEAD TO MORE EFFICIENT PURCHASING AND BETTER USE OF WARRANTIES

To determine whether hospitals were efficiently purchasing pacemakers in 1981, GAO evaluated the purchasing practices of the 12 reviewed hospitals and obtained data related to this area from the four manufacturers. Although the manufacturers made discounts available to hospitals, generally ranging from 5 to 40 percent depending on the quantity and type of pacemaker purchased, only three of the hospitals had obtained discounts. Based on the discount availability data GAO obtained, at least seven other hospitals could have obtained discounts. (See p. 25.)

GAO believes they did not because:

--The manufacturers did not advertise the discounts but rather waited for hospitals to seek them.

--Medicare's cost reimbursement system in effect in 1981 provided hospitals little incentive to seek discounts because they were paid their actual purchasing cost for pacemakers.

A hospital can enhance its ability to obtain discounts by (1) agreeing with its practicing physicians on the make of pacemaker that will normally be used and coordinating pacemaker purchases or (2) consolidating pacemaker purchases with other affiliated hospitals or with a group-purchasing organization. Of the 12 hospitals in GAO's sample, 1 was coordinating its pacemaker purchases and 2 were consolidating them. (See p. 28.)

To determine if hospitals were effectively using the benefits available under pacemaker warranties offered by two manufacturers on models replaced after they failed, GAO reviewed replacement surgeries at the 12 hospitals and obtained data from the manufacturers. Replacements accounted for about 19 percent of the 1,063 pacemaker surgeries at the 12 hospitals.

In many cases, GAO could not determine whether a warranty credit could have been received because the necessary data did not exist. However, GAO did identify cases where available information indicated that credits could have been available but the hospital had not returned the removed pacemaker to the manufacturer, which is a condition of the warranty. (See p. 14.)

GAO believes that a primary reason hospitals frequently did not seek warranty credits was that Medicare's cost reimbursement system did not give the hospital an incentive to obtain credits. Obtaining a credit only reduced Medicare's payment to the hospital, and Medicare paid for the replacement pacemaker if a credit was obtained.

Introduction in fiscal year 1984 of Medicare's prospective payment system, with its predetermined payment for each pacemaker case regardless of costs, has given hospitals financial incentives to be more cost-conscious purchasers of pacemakers and to seek warranty credits, thereby reducing their costs. Additionally, the two reviewed manufacturers that did not offer warranties in 1981 began doing so in 1984, so the availability of warranties has increased.

DATA HHS USED TO COMPUTE PROSPECTIVE PAYMENT RATES CONTAINED ERRORS

GAO compared the data it obtained at the 12 reviewed hospitals to the data HHS used to compute the prospective payment rates for pacemaker surgeries. GAO identified a number of problems, some of which indicate that the prospective payment rates may be too high and others which indicate that the rates may be too low. Specifically:

--The data HHS used were extracted from the unaudited cost reports for the 12 hospitals, as were the data for almost all of the hospitals involved in the rate computations. The eight cost reports that had been audited as of June 1984 showed lower costs than the unaudited reports. Ancillary service costs, which account for the majority of costs for pacemaker cases, averaged 5 percent lower in the audited cost reports than in the reports submitted by the hospitals. (See p. 33.)

--About 10 percent of the cases were classified in the wrong pacemaker DRG, usually a lower cost replacement being classified as an initial implant. These errors would tend to result in lower prospective rates for initial implants. (See p. 34.)

--About 40 percent of the pacemaker surgery cases were classified into nonpacemaker DRGs. Such errors tended to inflate the payment rates for the nonpacemaker DRGs because the DRGs to which the pacemaker cases were assigned covered less costly treatment. Including the pacemaker cases in the lower cost DRGs increased the average cost for those DRGs and thus increased payment rates. (See p. 35.)

--The process used to develop costs for computing the prospective payment rates resulted in inaccuracies because of hospital billing errors and placement of charges and costs in the wrong accounts. These problems could result in either overstatement or understatement of costs, depending on the specific facts in each case. (See p. 36.)

Additionally, one pacemaker DRG combined procedures involving significantly different levels of resource use, which is not supposed to be the case. DRG 117 includes procedures for replacing, removing, adjusting, or repositioning pacemakers or pacemaker leads (the wires connecting the pacemaker to the heart). Payment rates for each procedure under the DRG are the same even though, for example, replacing a lead costs substantially more than repositioning one.

PACEMAKER TECHNOLOGY AND MEDICAL PRACTICE IMPACT ON ADEQUACY OF PAYMENTS

GAO identified two issues relating to pacemaker technology and medical practice that HHS needs to address when it updates prospective payment rates. First, in 1981 only about 5 percent of the pacemakers implanted were the more sophisticated and costly dual chamber models. However, in 1984 an estimated 24 percent of pacemaker implants involved dual chamber models. (See p. 43.) Because dual chamber pacemakers and their implantation cost substantially more than single chamber models, there may be a need to establish separate DRGs for them to prevent an economic disincentive to the use of dual chamber pacemakers when such use is medically warranted.

HHS should also establish guidance on the medical conditions for which the use of the dual chamber models is appropriate to preclude the unnecessary use of this more expensive technology. HHS' current guidance on pacemaker use does not distinguish among the conditions for which single chamber versus dual chamber models are appropriate. (See p. 45.)

Another potential problem is that pacemakers are being replaced when still operating within specifications. Three manufacturers provided GAO data on the results of tests of over 10,000 returned pacemakers which showed that about 70 percent of them were operating within the manufacturers' specifications. (See p. 49.)

Physicians may replace pacemakers that are still functioning within specifications for various medical reasons, such as changes in a patient's condition. Manufacturers also cited the following nonmedical reasons: (1) marketing policies that provide for incentive payments from manufacturers to hospitals and doctors for pacemaker replacement and (2) inconsistencies between the standards used by physicians evaluating a pacemaker and the standards used by the manufacturer in factory testing pacemakers.

REMOVED PACEMAKERS SHOULD BE RETURNED TO MANUFACTURERS

Manufacturers test removed pacemakers when they are returned to determine if any problems, such as manufacturing defects or faulty parts, could adversely affect quality of patient care. GAO found that about 53 percent of the pacemakers removed at the sample hospitals were not returned to the manufacturers, precluding quality assurance testing. All four manufacturers estimated that a substantial portion of such pacemakers are not returned to them. This can inhibit the manufacturers' quality assurance programs. (See p. 22.)

Section 2304 of the Deficit Reduction Act of 1984 (Public Law 98-369) requires HHS to establish a registry of all pacemakers and leads implanted in Medicare beneficiaries and requires hospitals to report to HHS the information needed for the registry as a condition of receiving Medicare payment. The law also permits HHS to require hospitals to return all removed pacemakers to the manufacturers and to require the manufacturers to test all returned pacemakers and report the results.

HHS should use these authorities to require that all removed pacemakers be returned for testing. This would help strengthen controls over quality of care and give HHS the information necessary to know when warranty credits are issued. This information could in turn be used to assure that Medicare benefits from warranty credits. As of February 1985 HHS had not issued regulations implementing section 2304. (See pp. 20 and 24.)

RECOMMENDATIONS

GAO recommends that the Secretary of HHS:

--Require hospitals to return all removed pacemakers and leads to the manufacturers and require the manufacturers to test all returned pacemakers and leads and report the results to the hospitals. (See p. 21.)

--Direct the Administrator of the Health Care Financing Administration to revise Medicare's prospective payment rates using data reflecting current hospital pacemaker implantation costs. (See p. 31.)

--Direct the Administrator to determine (1) if the increased use of dual chamber pacemakers warrants establishment of separate DRGs for them, (2) the conditions under which the use of higher cost dual chamber pacemakers is medically appropriate, and (3) if the high percentage of functioning pacemakers that are replaced is resulting in unnecessary Medicare costs. (See p. 58.)

--Direct the Administrator to review the appropriateness of inclusion under the same prospective payment rate of both higher and lower cost pacemaker procedures. (See p. 40.)

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GAO did not obtain official comments on this report from HHS, the manufacturers, or the hospitals reviewed.

Chairman HEINZ. Let me start with Mr. Stollhans, of the FBI.

Mr. Stollhans, I understand that pacemaker kickback schemes are becoming more sophisticated and complex. Would a legal requirement that manufacturers disclose consultant arrangements be helpful to you?

Mr. STOLLHANS. I think it certainly would, because it would help, certainly from a deterrence standpoint because it obligates the individuals involved that if they are going to have any other financial relationship with a manufacturing company of pacemakers, that now they are declaring it in black and white that at least it exists. And, of course, if it would be found out that they would lie about that situation, of course, it is more damaging if it is investigated.

So, from a deterrence standpoint, I think it is very good. From a prosecutor's standpoint, if he does, in fact, lie to hide that relationship so that there is a way to receive some kind of kickback, as prohibited by the law, this is more blatant, more black and white, there is a longer audit trail, and it would be a much easier case to prove in a criminal court.

Chairman HEINZ. So, that would be a very helpful change in getting you to track down this new method of paying kickbacks?

Mr. STOLLHANS. I think it would be very helpful from both standpoints.

Chairman HEINZ. Very well.

Mr. Zimmerman, your report reveals that 70 percent of explanted pacemakers are found after testing to be functioning according to manufacturers' specs. Now we know that some of those are going to be taken out, as you mentioned in your report, for medical reasons.

There are also a variety of sales practices of manufacturing and companies to discourage warranty recoupment. Would you describe those incentives in a bit more detail?

Mr. ZIMMERMAN. There are a number of practices, as you mentioned, Senator. Manufacturers tend to offer incentive payments to replace defective pacemakers of other manufacturers with their own products.

As I pointed out, replacing one manufacturer's pacemaker with another's generally invalidates the warranty.

Also, in some cases, the manufacturers reduce commissions of sales representatives or distributors when a warranty credit is issued. This policy tends to discourage sales reps from providing for the return of explanted pacemakers to the manufacturer.

In our report, we point out a situation where a manufacturer's rep had his commission reduced by about $800 because of the return and replacement of a $4,000 pacemaker.

So, it appears to us, at least from what was going on when we did our work, that there are a number of marketing and incentive practices out there that discourage the sales reps from seeing that the warranties are achieved.

Chairman HEINZ. It is absolutely fascinating that the salesman should have to forego an $800 commission because the pacemaker was returned in some way. It would suggest that he was doing a bad selling job, keeping the pacemaker in the patient, as opposed to the doctor, who is doing a bad medical job, keeping the pacemaker in the patient.

Mr. ZIMMERMAN. The company may have hoped that the salesman would convince the provider not to return the pacemaker, and therefore preclude collecting the warranty. Maybe that is where the sales job fell down, on the subsequent purchase. He should have convinced them to seek some other avenue.

Chairman HEINZ. It is all right to replace them quite frequently, but just not to have the used one come back.

Mr. ZIMMERMAN. That sounds to me like the situation that existed.

Chairman HEINZ. Yes.

Now, isn't it also true with respect to hospitals, that it is at least theoretically possible, and may even be taking place, that under the current reimbursement system, prospective payment, the hospitals can now double dip—that is to say, if they get a defective pacemaker, one that is covered by the warranty, they can get the money back from the manufacturer—and indeed, the incentives were designed that way—but under PPS, they still get paid the same rate whether or not they got that pacemaker; in a sense, because Medicare never gets the benefit of that warranty, Medicare is under PPS paying twice. Is that correct?

Mr. ZIMMERMAN. I think it is correct to say that the hospital can receive two payments—one, from the manufacturer in terms of a warranty payment, if the hospital is fortunate enough to collect it; and one from the Government, under the Medicare Program. To the extent that the Medicare payment will be sufficient to cover the cost of the pacemaker and the warranty is sufficient to cover the cost of the pacemaker, then theoretically, a hospital could receive a duplicate payment.

Chairman HEINZ. Your report was fascinating in one other of many respects, which is that overseas, the intermediaries or the users tend to insist on a moneyback guarantee as opposed to replacement in-kind, and the bottom line is that the European customers seem to want a more complete warranty package and coverage than is commonly offered here in the United States.

Besides the difference between paying cash, moneyback, and the other alternative here, which is often replacement—in-kind, are there any other key differences?

Mr. ZIMMERMAN. I think the European warranties tend to extend for a longer period of time. But maybe Mr. Stropko could add something to that.

Mr. STROPKO. Actually, I think it is kind of a mixed bag. The major distinction that we saw was the moneyback feature, which precludes companies from denying a warranty on the basis of not using their product the second time around. So that was really the major difference, although individual countries did have, in individual instances, better warranty practices. But in other instances countries had practices that had warranties that were not as good as the United States.

So on balance, the major difierence seemed to be the moneyback guarantee.

Chairman HEINZ. It would seem on the surface to be in the interest of hospitals to shop around for a good warranty; that they, as the major purchasers of pacemakers, would have a good incentive to maximize the return to them. They are the people who are under prospective payment and fixed, per-diagnosis payments. Why are they not demanding moneyback guarantees?

Mr. ZIMMERMAN. I am not in a position, Senator, to explain why they are not demanding. I think the incentives are clearly in their behalf to be very aggressive in pursuing the best kind of arrangement today with the manufacturers of pacemakers to assure that they can make the best arrangement.

As to why they are not insisting on a moneyback guarantee, I really do not have an answer to that question.

Chairman HEINZ. One last point. You went to considerable length to explain earlier how the data that HHS has used to calibrate payments for pacemakers is out of date, and it is my understanding that HHS is planning to recalibrate the DRG's for this procedure.

Do you know whether they are going to use once again outdated information, or are they going to use the most current up-to-date information?

Mr. ZIMMERMAN. The only way they can really get at the issues that we are talking about in this report is to get current data representing data, I would say, from 1984 and later. That data will not be available for a period of time. So if they are going to be doing something now that does not include 1984 cost data that reflects what is going on currently, or in the recent past, under prospective payment, I do not believe they are going to be in a position to make the kinds of adjustments that we are talking about and that we think need to be considered and made recommendations about in this report.

They are going to need data that reflects the practices today of the industry, not what was going on in 1981, what was going on in 1982 or 1983. And I think they have to work toward that objective.

Chairman HEINZ. Very well. Gentlemen, I have no further questions.

Do either of you have anything you would like to add—Mr. Stollhans?

Mr. STOLLHANS. No, sir.

Chairman HEINZ. Mr. Zimmerman.

Mr. ZIMMERMAN. No, sir.

Chairman HEINZ. Well, let me just thank you both for some very illuminating testimony. I suppose it is not surprising, but it is always disappointing to hear that no matter how much effort has been made, there are still people out there, either still paying kickbacks, getting a little more sophisticated, a little harder to catch; that there is still a great deal of overutilization; that the incentives, even though they are improved, are still not as clear as we would like them to be; that the warranty problem, which was documented as massive in 1982, is still nonetheless a very real problem.

It seems to me, if I could summarize what we have learned from our five panels today, it would be first, that there really does need to be a lot of public education of doctors—remembering Dr. Phibbs' testimony—and of patients about the need to know more, but most importantly, to report problems—and this goes for the manufacturers, too—to report on problems, share a lot more of that information, particularly with respect to the kinds of problems that pacemakers indeed do encounter.

It is also my hope to get a commitment from the Office of Management and Budget with respect to the pacemaker registry, for them to be more fully cooperative with the needs of the Food and Drug Administration. I am convinced the FDA really does want to do the right thing. We have testimony from the industry—in this case, from Dr. Weldon, of Cordis, that he believes that a proper pacemaker registry could be extremely useful. The only argument, I think, that the Department of HHS, the Health Care Financing Administration, has is that they have different numbers than we and GAO and the PRO's have as to the potential returns to the Government in pursuing warranties more carefully. They have a $17 million recovery figure, and ours ranges all the way up to $80 million.

But even if the money angle is marginal in terms of cost benefit, there seems to be a big health benefit from keeping track of pacemakers much more accurately.

It clearly is going to also require a major effort on behalf of both HHS, FDA, HCFA, to make sure we do get all the information, and that will require the kind of cooperation, in terms of the dual-labeling that has been suggested here today, and as I understand it, endorsed as a reasonable procedure by Dr. Weldon and others. And finally, it has been suggested by Carolyne Davis that it would be useful for HHS to have some additional authority to clarify their ability to collect on warranties, although I sense from what Mr. Zimmerman was saying that they have a good deal of authority with respect to the hospitals right now, at least to get information, if not the money—is that correct?

Mr. **Zimmerman**. That is correct, sir. I think before they can start talking about making any gains in collecting money, they are going to have to get the information first to find out what kind of money they are talking about—is it $17 million; is it $80 million, just what is it.

I think Dr. Davis did allude to the fact that the information is lacking for them to make solid judgments as to just what the cost situation is as it relates to warranties.

Chairman **Heinz**. An important other conclusion is whether or not Congress or, for that matter, HCFA, should require providers to shop for a warranty that is a moneyback kind of warranty, whether or not we should provide that by statute, by regulation—it is probably controversial.

It does not seem to me, as a matter of principle, to offend the market principle that we should tell the Health Care Financing people and the providers to look for something that is most advantageous to them, inasmuch as they really are our agents; we ultimately pay those bills.

And finally, it is my hope that we will, by keeping an eye on this entire situation—and here, we commend the FDA for very thorough, painstaking work, even though I am sure it was uncomfortable to Cordis Corp.—that it is in the public interest that not only the FDA, but the Congress through oversight, keep our eyes on this industry. It has grown very rapidly over the last 15 years; pacemakers were invented, I guess, and really started to be used broadly as recently as 1973, as I recollect—maybe it is before that a few years. But it is at a point in time at which you are implanting up to 150,000 pacemakers—implanting and reimplanting—that is a major industry. It is a $2 billion a year industry if you include all the costs and the payments to doctors as well as the payments to the hospitals. And anything that has grown that fast is going to have some growing pains, and frankly, there will be some unscrupulous people in the industry, as Mr. Stollhans has so clearly documented. He has put people, if not behind bars, at least in community service, and on probation.

I do not know what it is you have to do these days to get behind bars—I certainly do not want to find out firsthand. But if I had to have anyone find out, Mr. Stollhans would be as good as any. He seems to have his priorities fairly straight.

That is probably not an exclusive list of all the things that I think the committee has learned today, but it is to my mind an extremely valuable and important list. And I want to thank not only you, Mr. Zimmerman, and Mr. Stollhans, and all the others, but I want to thank the people from the agencies who were here earlier. I want to commend the staff of the committee for having worked very hard to make sure that we did get into all of these issues. We do not have an oversight hearing on this kind of issue all that often. It has been 3 years. And if we are going to do it, we need to do it as well as we know how. And that is precisely what we have tried to do, and there is no doubt in my mind that from this we will have derived a number of legislative and other initiatives that we can shortly move on, and perhaps in budget reconciliation, which is now the next step after 3 a.m. last night.

So, I want to thank you all very much for being here. We appreciate your time and attention, your hard work. None of these pieces of paper that we skim through easily are produced in a matter of minutes or seconds. The committee is grateful to all concerned.

I thank you very much.

The hearing is adjourned.

[Whereupon, at 1:30 p.m., the committee was adjourned.]

APPENDIXES

APPENDIX I

May 9, 1985

PACEMAKERS REVISITED: A SAGA OF BENIGN NEGLECT

Section I: SUMMARY OF FINDINGS

1. Fraud, Waste, and Abuse Remain Prevalent in the Pacemaker Industry.

  o The Justice Department was successful last year in prosecuting two major pacemaker manufacturers for having paid hundreds of thousands of dollars worth of kickbacks to physicians, and the FBI is currently working on other such cases.

  o Under the new DRG system, Medicare provides incentives for hospitals to "double dip" from both Medicare and a pacemaker manufacturer, by collecting a warranty credit from the manufacturer for a pacemaker that is explanted and returned, and then also collecting a full DRG payment for the replacement surgery, which includes the price of the replacement pacemaker.

  o GAO's new report, "Medicare's Policies and Prospective Payment Rates for Cardiac Pacemaker Surgeries Need Review and Revision", identifies pacemaker manufacturer policies which provide for the manufacturer to deduct part of the sales representatives' sales commission when a warranty credit is issued for a returned pacemaker. One manufacturer's policy was to reduce the distributor's sales commission by $800 if a $4,000 pacemaker was returned and a warranty credit was issued.

  o As many as 30,000 of the estimated 110,000 initial pacemaker implants in older Americans projected for this year may be unnecessary.

  o The pacemaker industry's own testing of pacemakers that are removed and replaced has revealed that as many as 21,000 pacemaker replacement surgeries on older Americans this year may be unnecessary.

2. Pacemaker Surgery Causes Serious Medical and Social Complications for Older Americans.

According to expert testimony received by the Committee:

  o Unnecessary surgery results in part from physicians' poor understanding of electrocardiography and cardiac arrythmias. Physicians taking specialty examinations measuring these skills exhibit the highest failure rate in the field of cardiovascular disease -- yet these are skills required to make judgements of the need for pacemaker insertions. These findings indicate an immediate need for improved geriatric medical education, as well as strict and clear Medicare guidelines to define when surgery is needed.

- At least 2% of pacemaker patients suffer blood clots around the pacer lead which can cause major illness and death.
- From 1 to 5% of patients suffer an infection of the heart lining due to the pacemaker, the lead, or both, a potentially fatal complication. Treatment often involves major surgery to remove the device.
- Patients wearing pacemakers cannot obtain life insurance at reasonable rates, and sometimes not at all. Health insurance is very difficult to obtain, and many types of employment are severely limited for pacemaker patients.
- Psychiatric literature establishes that from 10 to 20% of pacemaker patients suffer severe depression, anxiety, disorientation associated with a loss of identity, and a variety of psychoneurotic disorders, all associated with the unacceptable notion that they are permanent cardiac patients, whose life depends upon a machine -- a serious problem, particularly in cases of unnecessary implants.

3. The Government's Medicare "Watchdogs", the Peer Review Organizations (PROs), Are Ineffective in Controlling Unnecessary Pacemaker Surgery.

- Despite their federal contract requirement for 100% review, PROs are reviewing only 35% of pacemaker implants, and are declaring a scant5.1% of these surgeries to be unnecessary.
- Most PRO review of pacemaker surgery is conducted after the surgery has already taken place and, therefore, cannot prevent unnecessary surgery before it happens.
- The government allows each of the PROs to independently formulate its own guidelines for determining the medical necessity of pacemaker surgeries, but this practice serves only to perpetuate the existing disparities in pacemaker surgery rates, disparities that now range as high as 1200% between localities.

4. Despite a Congressional mandate to cure the problem, the Health Care Financing Administration (HCFA) is less able today to recover Medicare's share of pacemaker manufacturer warranty credits than it was in 1982.

- HCFA could recoup for Medicare as much as $25 - $85 million annually from manufacturers for pacemaker pulse generators replaced or recalled while the device is still under warranty. Replaced or recalled warranteed pacer leads would provide additional funds.

- In only 26% of replacement surgeries were the PROs successful in obtaining all of the warranty information necessary for Medicare to recover monies under manufacturer warranties.

- The Health Care Financing Adminstration has failed to develop regulations that their internal memoranda indicate they believe are necessary for Medicare to recover any warranty monies.

- HCFA instructed all PROs in March of this year that they should cease gathering information on pacemaker warranties and replacement pacer leads.

5. The Marketing of Defective Pacemakers: Evidence of The Need for a National Pacemaker Registry.

- An ongoing FDA investigation of the Cordis Corporation, one of the largest pacemaker manufacturers worldwide, has revealed many serious problems and deficiencies in the firm's manufacturing and marketing operations, resulting in the distribution and implanting of thousands of potentially defective pacemakers.

- Upon FDA recommendation, the firm has notified physicians and hospitals of potentially life-threatening defects in pacemakers discovered by the company several years earlier.

- The FDA investigation found that Cordis was slow in investigating and evaluating complaints concerning health hazards from defective or potentially defective pacemaker products.

- FDA investigators discovered that the firm had recorded the destruction of an internal report concerning defective pacemaker batteries, and one Cordis official had deleted from another internal company memo information pertinent to the FDA investigation.

6. Confusion and Lack of Commitment Mark Federal Efforts to Implement a National Pacemaker Registry.

- Although Congress mandated that the Registry be in place by January 1, 1985, FDA and HCFA held their first "formal working group meeting" to discuss its implementation on April 5, 1985. A key outcome of that meeting was a decision to write to HCFA's Administrator to ask that someone be placed in charge of HCFA's Registry effort.

- HCFA transferred the job of collecting certain pacemaker replacement data from PSROs and Fiscal Intermediaries (FIs) to the PROs in February 1984 by writing the task into PRO contracts, and began to pay PROs to collect this information in July 1984. By December, HCFA's Bureau Chiefs had decided this duty should be performed by the FIs. In March 1985, HCFA wrote PROs to stop collecting this data because "the FDA now maintains a registry".

- OMB rejected DHHS' request for $1.2 million and 11 personnel for FDA to implement and maintain the Registry, leaving the agency to redirect scarce internal resources to meet its Congressional mandate.

Section II: Background

(1) Introduction.

More than a half-million Americans -- 80% of them Medicare beneficiaries -- currently rely on pacemakers to regulate their heartbeats. This year alone, some 140,000 Medicare beneficiaries are expected to undergo pacemaker implant and replacement surgery at a cost of $1.4 billion. Included in this number will be from 21,000 to 30,000 pacemaker replacement surgeries costing Medicare about $200 million.

The Senate Aging Committee's September 1982 hearing on "Fraud, Waste, and Abuse in the Medicare Pacemaker Industry" challenged the necessity of half of the annual Medicare expenditures on pacemakers and related professional services.

The 1982 hearing revealed: markups on pacemaker prices were as much as 560%; physicians were charging as much as $2,000 for pacemaker implants, although the procedure had been simplified and shortened; pacemaker warranties were virtually inoperative under Medicare; 30% to 50% of implants were unnecessary; and there were kickbacks to physicians in the form of cash payments, stock options and travel excursions. The Committee made several recommendations pursuant to these findings.

(2) Status of The Committee's 1982 Recommendations

- Congress should establish a price sensitive reimbursement system to reverse incentives for overpricing and kickbacks in health care system. Status:

  Congress enacted Medicare Prospective Payment System, a price-based reimbursement system;

- Congress should establish a National Pacemaker Registry to monitor performance and utilization of pacemakers, and to allow Medicare to recoup monies spent on replacing pacemakers still under warranty. Status:

  Congress enacted Heinz amendments (in the Deficit Reduction Act of 1984), including provisions that:

- -- Provided for a National Pacemaker Registry, to be in place at the Food and Drug Administration by January 1, 1985;
- -- Mandated new guidelines for monitoring of pacemakers;
- -- Mandated two reports on pricing of physician and hospital payment for pacemaker surgery, both to be completed by March 1, 1985;
- -- Empowered the Secretary of DHHS to require that explanted pacers be returned to the manufacturer for testing;
- -- Provided the Secretary with authority to deny Medicare payment to physicians and providers for failure to submit Registry information or for failing to return explanted pacemakers to manufacturers for testing.

o Department of Justice, and the FBI in particular should aggressively pursue allegations of kickbacks connected with pacemaker marketing and sales. Status:

The Justice Department obtained guilty pleas to criminal charges in 1984 against two pacemaker firms which admitted paying hundreds of thousands of dollars in kickbacks.

o It was recommended that the Secretary of DHHS:

- -- establish adequate medical guidelines to ensure appropriate utilization of pacemakers;
- -- reduce physician payment schedules for pacemaker surgery and monitoring;
- -- develop appropriate frequency schedules for pacemaker monitoring;
- -- ensure that warranties are credited to Medicare's purchase of pacemakers and leads.

Status:

- -- HCFA issued pacemaker-implant guidelines in March 1983, but has not kept current with the state of the art in cardiology, and has yet to publish guidelines for sophisticated dual-chambered pacers.
- -- HCFA's study of physician payment, due March 1st, is now scheduled for completion in late Summer.

- -- Amendments to The Deficit Reduction Act resolved monitoring schedule problems.
- -- Warranty recoupment is less possible today than in 1982.

o Committee Chairman Heinz also requested GAO to examine hospital and manufacturer pacemaker purchasing and warranty practices, and to review the appropriateness of Medicare payments to hospitals. Status:

The recently completed GAO study requested by the Special Committee on Aging emphasizes very strongly the need for a National Pacemaker Registry, and verifies many of the Committee's 1982 findings (for further information, please see attached GAO report and staff summary of report.)

Section III: The Committee's 1985 Follow-Up Investigation

In late 1984, Chairman Heinz initiated a Committee inquiry into utilization of procedures and services in the Medicare program. Part of that inquiry included a follow-up investigation of the Committee's findings and recommendations from its 1982 pacemaker inquiry. This follow-up inquiry has revealed continued pacemaker overutilization and lack of Federal control.

(1) Continued Fraud and Abuse in the Pacemaker Industry

Kickbacks, consisting of money or favors paid by pacemaker manufacturers to physicians in order to induce demand, were outlawed in 1977 and identified as a major problem by the Committee in 1982. At the 1982 hearing, the FBI was encouraged to aggressively pursue criminal prosecution of pacemaker firms engaging in these practices. There have been two criminal convictions since that time:

o On October 12, 1983, Pacesetter Systems Inc. (PSI) of Sylmar, California, was indicted on four counts of Offering to Pay and Paying Kickbacks, and one count of conspiracy. In addition, the former President of PSI was indicted for 19 counts of Offering to Pay and Paying Kickbacks, and one count of conspiracy. A Regional Sales Manager and a Vice-President of the firm were also indicted on one count each of similar charges. In late 1983 and early 1984, these officials pleaded guilty, except the former President, who pleaded nolo contendere, to the charges brought against them.

o On July 6, 1984, Telectronics, an Englewood, Colorado based pacemaker manufacturer, pleaded guilty to four counts of having paid kickbacks totalling $134,050 to a cardiologist in Rhode Island and leasing equipment valued at $9,065 for the exclusive use of a cardiologist in New Port Richey, Florida.

The FBI has also uncovered more sophisticated kickback schemes such as equipment tradeoffs and phony consulting arrangements involving payments by pacemaker firms of fixed amounts per pacemaker implant to physicians to monitor the firm's products in the physician's patients. One physician reportedly received $150,000 over a two year period under a fixed consulting arrangement. According to the FBI, these types of schemes are extremely difficult to differentiate from legitimate research under present disclosure laws.

The FBI believes the National Pacemaker Registry could serve as an investigative tool. Further, the Bureau endorses the concept of requiring pacemaker manufacturers to fully disclose contracts and agreements with physicians for consultation and testing of pacemaker products in human subjects. Such disclosure would facilitate investigations of the more sophisticated kickback schemes.

(2) Pacemaker Overutilization Remains Largely Unabated

a. Kickbacks and Manufacturer Incentive Programs May Induce Physicians to Perform Surgery:

Where pacemaker firms provide financial kickbacks to physicians, they may encourage additional surgeries to be performed on patients that otherwise might have been recommended for medical treatment for their condition, or for whom a pacemaker is of no value.

b. Much Pacemaker Replacement Surgery May be Unnecessary:

Avoidable or Unnecessary pacemaker replacement surgery results from:

- "prophylactic explantation" of pacemakers and leads suspected of serious and life-threatening defects;
- manufacturers' financial incentives for physicians to purchase pacemakers, particularly to buy "upgraded" replacements of greater sophistication and higher cost;
- Medicare reimbursement incentives, particularly to replace pacers with "upgraded" models, for which surgeons' fees are higher;
- poor Medicare criteria for reimplanting pacemakers.

GAO's new report, "Medicare's Policies and Prospective Payment Rates for Cardiac Pacemaker Surgeries Need Review and Revision", presents data from its review of four pacemaker manufacturers (which account for some 80% of U.S. pacer sales) and audit of 1,063 pacemaker surgeries at 12 hospitals, which suggests that replacement surgery frequently may be unnecessary:

- Replacement surgeries accounted for an average of 19% of all pacemaker surgeries at these hospitals;

- Overall, the four manufacturers stated that about 70% of the pacemakers surgically explanted and subsequently returned to them for testing turned out to be operating within specifications. There was a great deal of variation between individual manufacturers in the proportion of explanted pacemakers the firm said were still operating properly at the time of explant. For example:

  -- Of 1,196 pacemakers explanted and returned to one firm for evaluation, about 33% were operating within specifications;

  -- Of 5,400 pacers explanted and returned to another firm for testing during a recent 36 month period, 80% were found to be operating within specifications.

Of the estimated 30,000 explant surgeries that will be performed in 1985, then, it appears that manufacturers could challenge -- on technical grounds -- the need for up to 21,000 of these surgeries.

Yet, the exact proportion of unnecessary replacement surgeries suggested by the manufacturers' test results remains unknown. HCFA figures from their Bureau of Quality Control (BQC) study state that over 12% of all replacement surgeries are performed on patients wearing recalled pacemakers (see below for further discussion on recalls and the BQC study), but these are pacemakers which manufacturers generally do recognize as covered under warranty. Whether as much as 70% of replacement surgeries are truly unnecessary cannot be ascertained without case by case medical review, using appropriate criteria of medical necessity.

Moreover, manufacturers' assessments of returned pacemakers' functional status may not represent the degree of unnecessary surgery because of different financial and other incentives affecting physicians and manufacturers. For example, some physicians may desire to promptly explant a pacemaker with declining function as it nears its End of Life, even if it is still operating within technical parameters set by the manufacturer. Manufacturers' judgements, on the other hand, may be influenced by an incentive to limit outlays for warranties on pacers and leads that fail. Both factors would tend to inflate the number of pacemakers explanted but judged to be functioning within manufacturer specifications.

c. Millions of dollars each year in manufacturer warranty credits are potentially available to Medicare.

For those pacers that manufacturers are willing to acknowledge have failed during the term of a warranty, Medicare could recover millions of additional dollars annually, if it had a mechanism for taking advantage of such warranty coverage (please see Section IV, below, for further discussion of Medicare and pacemaker warranties).

d. Recalls Of Defective Pacemaker Products Have Increased Substantially Since 1982

The only available data on pacemaker replacement surgeries caused by recalls of defective devices is a pilot study conducted by HCFA's Bureau of Quality Control (BQC) and based upon 1982 data. This study found that about 12% of all pacemakers replaced in that year were replaced after a manufacturer recall (either voluntary or an FDA-ordered recall) of the device.

This proportion has probably increased dramatically since the 1982 study, as the number of recalled pacemaker devices has increased. BQC's estimate, therefore, of the number of explant surgeries may be too small, in that their estimate of recalled pacers for each year (12% of the annual number of expected replacement surgeries) is based on recalled pacers explanted from patients during 1982, a year in which relatively few pacers were recalled.

In terms of financial impact BQC estimates that Medicare will spend $30 million in 1986 to explant recalled pacemakers. Because the number of recalls has risen steadily each year since BQC's estimate, it may represent only 33 to 50% of the actual cost to Medicare for these surgeries, potentially $60 to $90 million annually.

The following table depicts the total annual number of recalled pacemakers and leads according to FDA, compared to the BQC study estimates for replacement surgeries:

Year	# Replaced Pacers & Leads (Projected by BQC)	Actual # Recalls (FDA Records)
1982	2460	7,525
1983	2675	10,878
1984	2846	18,000 - 26,000*
1985	3016	over 22,000+

Notes:

* The exact number of recalled pacer leads in 1984 was unavailable.

+ Estimated number of recalled pacers still implanted in patients at the time of the recall.

Section IV: Confusion and Lack of Commitment Mark Federal Action to Implement the National Pacemaker Registry and to Recover Pacemaker Manufacturer Warranty Monies

(1) Implementation of the National Pacemaker Registry

The Heinz amendments to the Deficit Reduction Act of 1984 created a National Pacemaker Registry at the FDA to provide for a registry of all pacemaker devices and leads for which payment is made under Medicare. The purposes of the Registry are:

o to identify defective pacemakers and pacer leads as specific models are found be developing a pattern of premature or hazardous failure;

o to protect beneficiaries from such defective devices, by ensuring that the location of each defective pacer is known, including the identity of implanting physicians and the patients dependent on the devices, so they may be notified of potential and actual hazards associated with the device;

o to ensure that Medicare is able to recover warranty monies on pacemakers that fail during the manufacturer's warranty period.

The new law established a deadline of January 1, 1985 for the creation of the Registry and for implementation of the related regulations.

The law specifies that the Registry must contain information including at least the manufacturer, model, serial numbers, date and geographic location of the implantation or removal, and any express or implied warranties. The law requires submission of this information to the Registry as a condition of Medicare payment. Under the new law, the Secretary may also require providers to return explanted pacemakers to manufacturers for analysis, and may condition reimbursement to the provider on compliance with this provision. The Secretary may require manufacturers to test explanted devices, and to share the test findings and related warranty information with providers. Finally, the Secretary may dispatch FDA personnel to observe manufacturer testing of explanted pacers.

Two components of the Department of Health and Human Services, the Health Care Financing Administration (HCFA) and the Food and Drug Administration (FDA), must collaborate and share information in order to implement the terms of the Heinz Amendments.

HCFA, as the agency responsible both for financing and controlling utilization of pacemaker surgery under Medicare, can identify data on each pacemaker surgery paid for under Medicare, including specific information on the device, patient, provider, and date of the procedure.. Also, HCFA alone is able to determine if the surgery being performed is a replacement of a particular patient's pacemaker, an initial implant, or another pacer-related procedure.

As the agency responsible for administering Medicare, HCFA has the most experience at gathering data for the purpose of ensuring that the program recovers monies owed to it as the purchaser of devices that fail while covered under a manufacturer's warranty. A series of HCFA contractors -- first the Professional Standards Review Organizations (PSROs) and Fiscal Intermediaries (FIs), and now the Peer Review Organizations (PROs) -- have been gathering pacemaker reimplant and warranty data for these purposes since at least October, 1983.

FDA is responsible for providing the staffing and other resources necessary for the Registry. The agency already maintains computer data bases detailing pacemaker and pacemaker lead failures, as well as records of all recalls of defective devices. FDA's existing information on recalls should be valuable to HCFA, to assist that agency in recouping Medicare monies expended for pacers and related devices that are recalled or fail while still under manufacturer warranty.

It may appear that these two agencies are well prepared, by virtue of their existing duties and authorities, to collaborate on the implementation of a National Pacemaker Registry. Yet, despite the Congressionally mandated deadline of January 1, 1985, the National Pacemaker Registry and the regulations necessary to maintain and enforce it are not yet finished. In fact, FDA now estimates the completed regulations will not be issued until December, 1987.

There are several reasons for DHHS' delayed implementation of the Heinz amendments, but the most significant of these is that HCFA's efforts to control pacemaker utilization and recover Medicare's share of warranty monies have been largely unsuccessful. The agency's past and present failures in this regard threaten to cripple the new pacemaker Registry.

HCFA has allowed its PROs to utilize antiquated review methodologies and criteria to monitor and evaluate the appropriateness of implant/explant surgery:

o The agency has not updated its criteria for appropriate pacemaker-implant guidelines since 1983, despite the publication in late 1984 of new and more strict criteria developed by cardiologists.

o PRO denials are based on "retrospective review" of medical records, occurring after patients have undergone life-threatening surgery, and after hospitals and physicians have incurred unnecessary and non-reimburseable expense.

o HCFA has allowed the PROs to slip far behind in their contractually-required 100% review of pacemaker surgeries (PROs report having reviewed pacer surgeries at an annual rate of only 40,000 surgeries, compared to the estimated 140,000 annual surgeries expected to occur).

o HCFA has decided that pacemaker review by the PROs should be reduced in the future.

o HCFA has also been hampered by infighting between two key HCFA offices, the Health Standards and Quality Bureau (HSQB), and the Bureau of Program Operations (BPO). The Bureaus have been quarreling over which of them should be responsible for supervising the gathering of warranty information. In March of this year HSQB -- the winner of the internal debate -- issued program instructions to the Peer Review Organizations (PROs), informing them that as of March 25, 1985, they were relieved of the responsibility for gathering data on pacemaker leads and warranties, both items needed for the Registry.

o Although the Registry is to be maintained at FDA, FDA must depend upon HCFA to send certain essential information -- including pacemaker replacement and warranty information -- over to FDA at regular intervals, for updating the Registry data base. Yet, as of April 1985, HCFA still had no single person coordinating the agency's response to the mandate of DEFRA.

(2) Medicare and Pacemaker Warranties: HCFA Steps Backward

The Health Care Financing Administration (HCFA) administers the Medicare program, and has primary responsibility for monitoring the quality and quantity of pacemaker services provided to program beneficiaries. There have been a number of problems with HCFA's previous efforts to use the PROs to review 100% of pacemaker reimplants and to gather warranty information for these reimplants. Now, perhaps in recognition of these problems, HCFA intends to spend another million dollars to prepare the fiscal intermediaries (FIs)to collect this information.

Prospects for the success of the FI reimplant review are poor. HCFA spent months developing a draft reimplantation data collection form to convey to FDA for comment. Each successive draft look like the other, largely because all of the data elements on each draft were specified in the Deficit Reduction Act. Yet, while early drafts of the form would have assured all essential warranty information was gathered and reported to the Registry, the draft HCFA finally sent to FDA in April, 1985, omits any reference to warranty data.

Internal memoranda from HCFA indicate that, under Prospective Payment it is no longer possible for Medicare to realize any recoupment from warranties -- at least until a new DRG category accounting for warranty credits, or a lawful way of witholding portions of DRG payments, is created. These memoranda reveal that HCFA has apparently decided the government has inadequate authority to recover money from manufacturers based on warranties, but has taken no known action to secure such authority, either through Congress or new regulations.

Yet, a considerable amount of money is potentially recoverable from manufacturer warranties for pacemakers, initially purchased by Medicare, which must be replaced due to failure or recall.

To find out how much warranty money HCFA could potentially recover, Committee staff analyzed 336 monthly reports submitted by Peer Review Organizations (PROs) from 49 States and the District of Columbia. These monthly reports describe the outcome of the PROs' contractually mandated 100% review of approximately 14,000 pacemaker surgeries between July 1984 and February 1985.

A STUDY OF PRO PACEMAKER REVIEW ACTIVITY

(a)	Projected Annual # Reviews (from best month):	48,480
(b)	Projected Annual % of Medicare Surgeries Reviewed:	35%
(c)	Total # Reimplants Identified:	1,014
(d)	Percent of Surgeries PROs Identified as Reimplants:	2.9%
(e)	Total # Reimplants For Which PRO Reported All Necessary Warranty Information:	268
(f)	Percentage of Reimplants For Which PRO Reported All Necessary Warranty Information:	26.4%
(g)	Number Pacers Explanted During Warranty Period:	188
(h)	Percentage of All Explanted Pacers Which Were Explanted During Warranty Period:	70.0%

This analysis reveals that, of the 268 explanted pacemakers for which PROs had gathered all the warranty information necessary determine if the pacer was removed during the warranty period, fully 70% of the pacers were replaced during the manufacturer's warranty period. If HCFA were to gather all the necessary data, and hospitals were required to return explanted pacemakers to the manufacturer for testing, between $25 and $84 million annually in manufacturer warranty refunds could potentially be recovered for the financially-strapped Medicare Trust Fund.

In addition, the PROs are identifying only 2.9% of all pacemaker surgeries as replacement surgeries. This figure is compares with GAO's estimate of 19%, and HCFA's pilot study by the Bureau of Quality Control (BQC), which estimated that 21% of all pacemaker surgeries are for replacement of a pacer. The proportion of replacements may have gone dramatically downward since 1981 and 1982, the period which the GAO and BQC studies focused on, or the PROs may be failing to properly identify a significant number of replacement surgeries. HCFA will need to understand the reason for this problem, even if the fiscal intermediaries begin to monitor replacement surgeries, instead of the PROs.

Section V: FDA Investigation of Cordis Corporation: A Case Study.

The Cordis Corporation, one of the largest pacemaker manufacturers with worldwide sales of $132 million in 1984, has been the target of a lengthy and ongoing FDA investigation since early December 1983.

FDA investigators have documented many serious problems and deficiencies in the firm's manufacturing and marketing operations that presented potentially life-threatening health hazards to thousands of pacemaker patients. The FDA addressed these "serious health concerns" in a letter to Cordis dated September 7, 1984, and stated that "the problems *** appear to reflect a corporate practice and a pattern of serious disregard for the requirements of the Federal Food, Drug and Cosmetic Act."

Much of the FDA inquiry was prompted by information and internal Cordis documents supplied to the FDA by anonymous sources, beginning in October 1983. The following are summaries of several of the FDA's major findings:

(1) Early Battery Depletion in Gamma Model Pacemakers

On October 21, 1983, FDA Headquarters received in the mail from an anonymous source a copy of an internal Cordis report titled "Special Audit - Gamma Battery Cell Depletions." The report was the product of an special internal Cordis problem investigation devoted to study of the "134 premature Gamma Battery depletions...confirmed to date". The finished report identified "many process anomalies..." in manufacturing and quality control that "...indicate an overall lack of control".

The FDA initiated its investigation at Cordis in early December 1983, after receiving official word from the Company that it had mailed to physicians on December 2, 1983, an "Urgent Medical Device Notification" on "early battery depletion" in certain of the firm's Gamma series pacemakers. Upon being asked by FDA investigators for a copy of the Cordis battery depletion report, a Company official stated that all copies had been destroyed (see attached copy of the destruction record). According to the FDA, the firm did finally produce a copy after being told that failure to do so would be considered as "an inspectional refusal." A Cordis official also provided FDA investigators with a heavily altered version of a memorandum dated August 19, 1983, which instructed an separate internal Cordis task force on what to consider in studying the premature battery depletions.

Among the FDA findings were that the company had in 1980 made an improvement in the Gamma battery as protection against premature depletion of power. The firm, however, continued to sell more than 6,000 Gamma pacemakers containing the unprotected batteries between 1980 and August 1983. Cordis officials deny having had sufficient information that would have prompted earlier notification of physicians and a halt to sales prior to the firm's task force study concerning the early battery depletion problem.

FDA investigators reported that "As of February 1, 1984, there were a total of 270 expired patients that had Gamma pacers" with the unprotected batteries. The FDA report stated: "Prior to this inspection, no effort had been made (by Cordis) to determine if the recognized pacemaker early battery depletion failure mechanism could have resulted in a patient death that may have been mistakenly attributed to non-pacemaker related causes because a physician had no reason to suspect early pacemaker failure."

The FDA reports that, as of April 1, 1985, a total of 2,053 implanted Gamma pacemakers containing batteries subject to early battery depletion had failed prematurely.

(2) Wiring Defect In Certain Lambda, Theta And Stanicor pacemakers

In June 1984, FDA investigators discovered that Cordis had distributed more than 20,000 Lambda, Theta and Stanicor pacemakers that potentially could go into sudden "no output" failure due to a wiring defect.

The FDA investigation further revealed that, in September 1980, the Company had taken action to correct the defect after having received "at least 10 complaints on Lambda Model 190A pacemaker failures because of the wiring defect. The FDA reports, however, that following the firm's correction of the problem in 1980, Cordis "failed to repair" those pacemakers already in inventory and continued to sell more than 3,000 of these defective devices as late as the summer of 1983.

In September 1984, the FDA informed Cordis: "Based on the data that we have obtained, we believe that these deficiencies expose pacemaker dependent patients to potential serious adverse health consequences as a result of sudden no output failure."

FDA investigators found that the firm had "not conducted adequate investigations to determine the extent of injuries reported by patients having their pacemakers fail" due to the wiring defect.

Cordis had forwarded to physicians in 1982 and 1983 "Product Updates" in which the company warned that there was a problem with several of the models affected by the wiring defect. The FDA, however, determined that these notices were inadequate. As a result, on April 19, 1985, Cordis forwarded to 15,000 physicians an "Important Medical Device Notification" concerning "Potential Sudden Loss Of Output" in these pacemakers. The notification stated: "Cordis recommends that physicians reassess the pacer-dependency of their patients with the above models and prophylactically replace the pacemakers in totally pacemaker-dependent patients."

(3) Pacemakers Subjected To High Temperatures During Testing

FDA investigation revealed that Cordis had inadvertently subjected more than 250 pacemakers to temperatures almost 30 degrees above the boiling point (239 degrees F.) during testing. According to the FDA, the pacemakers were distributed and approximately 150 were implanted in patients, both in the U.S. and in foreign countries. The batteries in some of these pacemakers were replaced before distribution.

In its September 7, 1984, letter to the company, FDA stated: "In our opinion, pacemakers subjected to high temperatures for undocumented periods of time mayn result inm serious adverse health consequences in pacemaker dependent patients as a result of early battery depletion and sudden no-output failure." The FDA recommended that Cordis notify "all physicians and hospitals to whom these pacemakers have been distributed." According to the FDA, Cordis did send out notification in the U.S., but believes it is not required to send similar notification to foreign countries where more than a hundred of the heat-stressed pacemakers were distributed for implant.

(4) Delays In Evaluating And Investigating Potential Health Hazards

FDA investigation determined that Cordis' system for handling and investigating complaints concerning potential health hazards from its pacemaker products was deficient. For example, it was not until FDA investigators had brought several cases to the attention of the company that hazard assessments were finally conducted. The following are examples: (a) "an individual who blacked out while driving a car whose pacer was found to be dead"; (b) a patient whose pacemaker "had a rate decrease and also was reported to be a runaway pacemaker at 160-170 pulses per minute"; and (c) a pacemaker that "was explanted due to a rate decrease with a complaint that the patient experienced dizzy spells." Cordis complied with FDA recommendations and improved its system of evaluating and investigating such complaints.

Cordis states that it has made improvements in response to FDA inspections, and is in the process of effecting other improvements.

Appendix II

JOHN HEINZ, PENNSYLVANIA, CHAIRMAN

WILLIAM S. COHEN, MAINE
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STEPHEN R. McCONNELL, STAFF DIRECTOR
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United States Senate
SPECIAL COMMITTEE ON AGING
WASHINGTON, DC 20510

April 8, 1985

Frank Young, M.D., Ph.D.
Commissioner
Food and Drug Administration
Department of Health and Human Services
5600 Fishers Lane
Rockville, Maryland 20857

Dear Dr. Young:

As Chairman of the Special Committee on Aging, I am writing to request your assistance in the Committee's ongoing inquiry into utilization of services and procedures in the Medicare and Medicaid programs.

Specifically, I am requesting that the Food and Drug Administration (FDA) provide to Committee staff full access to all correspondence, memoranda, establishment inspection reports and attachments, computer and word processor-stored data and information, and any other records and documentation pertaining to the regulation of medical device use. It is essential for Committee staff to have free and complete access to these materials in order for the Committee to thoroughly evaluate the FDA's effectiveness and efficiency in regulating utilization of medical devices.

Should any of these materials contain trade secret or sensitive information from an ongoing FDA inspection, you have my personal assurance that such records and information will receive appropriate treatment.

Thank you for your assistance and cooperation in this matter.

Sincerely,

John Heinz

JOHN HEINZ
Chairman

JH:jmw

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
Rockville MD 20857

APR 17 1985

The Honorable John Heinz
Chairman, Special Committee on Aging
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

Thank you for your letter of April 8, 1985 to Commissioner Young regarding your Committee's investigation of medicare/medicaid issues in general and in particular medical devices, many of which are reimbursed under these programs.

We appreciate the fact that your staff have been following Department procedure in arranging for meetings and record reviews in advance and in coordinating these matters with the Office of Legislative Affairs.

In response to your request, conveyed by James Michie of the Committee staff, we are enclosing documents relating to FDA's open investigation of Cordis Corporation. These documents involve an ongoing investigation, and information set forth in the documents could lead to a recommendation for legal action. We are sure you appreciate the need to preserve the integrity of FDA's investigation by maintaining the confidentiality of the documents and will therefore understand that no part of the documents should be disclosed to any member of the public. Also many of the these documents contain confidential/commercial information which would not be releasable under FDA's Freedom of Information regulations.

We will be pleased to continue to cooperate with Committee staff in providing orderly access to Agency personnel and records.

Sincerely yours,

Henry H. Dausch
Henry H. Dausch
Acting Associate Commissioner
for Legislative Affairs

Enclosures
(w/ list of documents provided)

JOHN HEINZ, PENNSYLVANIA, CHAIRMAN

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United States Senate
SPECIAL COMMITTEE ON AGING
WASHINGTON, DC 20510

April 18, 1985

The Honorable Carolyne K. Davis, Ph.D.
Administrator
Health Care Financing Administration
314G Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Dr. Davis:

As Chairman of the Special Committee on Aging, I am requesting that you appear before the Committee on the morning of April 30, 1985, to testify on HCFA's responsibilities under Section 2304 of the Deficit Reduction Act of 1984.

As you know, Section 2304 includes several provisions that impact upon the Health Care Financing Administration (HCFA): establishing a National Pacemaker Registry with a deadline of January 1, 1985, for implementation; a study of "the appropriateness of the amounts recognized as reasonable under Part B of Title XVIII of the Social Security Act for physicians' services associated with implantation or replacement of pacemaker devices and pacemaker leads" with a report due on March 1, 1985; and regulations for establishing the pacemaker registry and for requiring the testing by manufacturers of explanted pacemakers to determine whether the devices are defective.

The registry was designed to protect Medicare beneficiaries from defective pacemakers and unnecessary pacemaker implants, as well as providing Medicare with a means to recoup on defective pacemaker warranties. Committee inquiry indicates, however, that establishment of the pacemaker registry and promulgation of the regulations required for operation of the registry and testing of explanted pacemakers are experiencing lengthy delays.

I, therefore, would very much appreciate your addressing the following questions in your prepared testimony:

1. What is the current status of HCFA efforts to assist the FDA in establishing the registry and promulgating regulations required for operation of the registry and testing of explanted pacemakers?

2. Does HCFA believe it has sufficient authority to promptly recover monies owed the Medicare program for pacers which fail due to defects and are explanted during the term of an applicable warranty?

Page Two
Letter to The Honorable Carolyne K. Davis

3. Why did HCFA decide to terminate the contractual obligation of the utilization and quality control Peer Review Organization (PROs) to collect information on pacemaker implants and reimplants necessary to recoup warranty monies?

4. What is HCFA's assessment of the historical effectiveness of the PROs at performing the contractually required collection of warranty information?

5. What provision has HCFA made to ensure that such information is now being obtained from physicians and providers by some other qualified entity?

6. What is HCFA's estimate of the amount of revenue which could be recouped by Medicare if it could collect on all warranties covering defective pacemakers and leads? What is HCFA's estimate of the cost of such an effort to recoup these warranty monies?

7. Has HCFA recouped any monies from warranted, defective pacemakers to date? How much, if any? If HCFA has not recouped any monies from such pacemakers, what is your best estimate of the date by which we may expect to recoup our first dollar of warranty recoveries?

Please provide the Committee with ten copies of your testimony by close of business on April 26, 1985, and an additional 100 copies on the morning of April 29, 1985. Your testimony for submission into the record may be whatever length you deem appropriate. We would appreciate your limiting your oral remarks before the Committee to approximately five minutes.

Should you have any questions regarding the hearing, please have your staff contact James Michie or David Schulke of the Committee staff at 224-5364.

Thank you for your cooperation and assistance.

Sincerely,

JOHN HEINZ
Chairman

JH:jmm

JOHN HEINZ, PENNSYLVANIA, CHAIRMAN
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United States Senate
SPECIAL COMMITTEE ON AGING
WASHINGTON, DC 20510

April 18, 1985

Norman R. Weldon, Ph.D.
President
Cordis Corporation
P.O. Box 025700
Miami, Florida 33102

Dear Dr. Weldon:

As Chairman of the Special Committee on Aging, I am requesting that you appear before the Committee on the morning of April 30, 1985, to share with us the Cordis Corporation response to the Food and Drug Administration's investigation initiated in late 1983 and pertaining to your firm's cardiac pacemaker/lead manufacturing practices and compliance with FDA regulations.

The Committee also would be very much interested in your thoughts and views regarding the establishment of a National Pacemaker Registry and the testing by manufacturers of explanted pacemakers as provided for in Section 2304 of the Deficit Reduction Act of 1984.

Please provide the Committee with ten copies of your testimony by close of business on April 26, 1985, and an additional 100 copies on the morning of April 29, 1985. Your testimony for submission into the record may be whatever length you deem appropriate. We would appreciate your limiting your prepared remarks before the Committee to approximately five minutes.

Should you have any questions regarding the hearing, please have your staff contact James Michie or David Schulke of the Committee staff at (202) 224-5364.

Thank you for your cooperation in this important matter.

Sincerely,

John Heinz

JOHN HEINZ
Chairman

JH:jmm

JOHN HEINZ, PENNSYLVANIA, CHAIRMAN

WILLIAM S. COHEN, MAINE
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STEPHEN R. McCONNELL, STAFF DIRECTOR
DIANE LIFSEY, MINORITY STAFF DIRECTOR

United States Senate
SPECIAL COMMITTEE ON AGING
WASHINGTON, DC 20510

April 18, 1985

The Honorable Frank Young, M.D.
Commissioner, Food and Drug Administration
Department of Health and Human Services
5600 Fishers Lane
Rockville, Maryland 20857

Dear Dr. Young:

As Chairman of the Special Committee on Aging, I am requesting that you appear before the Committee on the morning of April 30, 1985 to testify on FDA's role in regulating and monitoring utilization of cardiac pacemakers and associated devices.

As you know, section 2304 of the Deficit Reduction Act of 1984 includes provisions for establishing a National Pacemaker Registry with a deadline of January 1, 1985 for implementation. The registry is to contain data on all pacemaker implants and replacement implants, as well as pacemaker warranty information. The registry was designed to protect Medicare beneficiaries from defective pacemakers and unnecessary pacemaker implants, as well as providing Medicare with recoupment on defective pacemaker warranties. Committee inquiry indicates, however, that establishment of the registry itself and promulgation of the regulations required for operation and maintenance of the registry are experiencing lengthy delays.

I, therefore, would very much appreciate your addressing the following questions in your prepared testimony:

1. What is the current status of FDA efforts toward establishing the pacemaker registry and promulgating regulations required for operation and maintenance of the registry?

2. What is the FDA's current timetable for the registry to become fully operational?

3. When will the regulations concerning the return to, and testing by, manufacturers of explanted pacemakers become effective?

4. What are the causes of the delays in establishing the pacemaker registry and in promulgating the regulations?

5. Has the Health Care Financing Administration agreed to collect all the data, including warranty information, sufficient to fulfill the requirements of Section 2304 of the Deficit Reduction Act of 1984?

Page Two
Letter to The Honorable Frank Young, M.D.

6. How does the FDA intend to use its Medical Device Reporting and Device Experience Network systems in conjunction with the pacemaker registry?

7. In your opinion, do findings in FDA investigations of policy, practice and procedure in pacemaker manufacturing and utilization underscore the need for, and importance of, the Pacemaker Registry and the other FDA device reporting systems?

8. What is the status of the FDA's investigation of the Cordis Corporation's compliance with Federal regulations governing manufacturing and reporting requirements for cardiac pacemakers and leads?

Please provide the Committee with ten copies of your testimony by close of business on April 26, 1985, and an additional 100 copies on the morning of April 29, 1985. Your testimony for submission into the record may be whatever length you deem appropriate. We would appreciate your limiting your prepared remarks before the Committee to approximately five minutes.

Should you have any questions regarding the hearing, please have your staff contact James Michie or David Schulke of the Committee staff at 224-5364.

Thank you for your continuing cooperation and assistance.

Sincerely,

John Heinz

JOHN HEINZ
Chairman

JH:dsm

JOHN HEINZ, PENNSYLVANIA, CHAIRMAN

WILLIAM S. COHEN, MAINE
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STEPHEN R. McCONNELL, STAFF DIRECTOR
DIANE LIFSEY, MINORITY STAFF DIRECTOR

United States Senate
SPECIAL COMMITTEE ON AGING
WASHINGTON, DC 20510

April 19, 1985

The Honorable Charles A. Bowsher
Comptroller General of the United States
U.S. General Accounting Office
Room 7000
441 G Street, N.W.
Washington, D.C. 20548

Dear Mr. Bowsher:

As Chairman of the Special Committee on Aging, I am requesting that you appear before the Committee on the morning of April 30, 1985 to testify on GAO's findings in its major study of cardiac pacemaker reimbursement, utilization and warranty practices under Medicare's cost-based and prospective payment systems for hospitals.

As you know, section 2304 of the Deficit Reduction Act of 1984 includes provisions for establishing a National Pacemaker Registry. The Registry is to contain data on all pacemaker implants and reimplants, as well as pacemaker warranty information. The Registry was designed to protect Medicare beneficiaries from defective pacemakers and unnecessary pacemaker surgery, as well as to provide Medicare with recoupment from defective pacemakers covered by warranties. In addition, the Act calls for studies of the appropriateness of current prices Medicare pays for such surgery under Part A and B.

I therefore would very much appreciate your focusing your prepared remarks on the following issues:

1. Pacemaker purchasing practices prior to the implementation of PPS compared with current incentives, and the effect of these practices on the PPS rates now being paid.

2. Hospital practices regarding explantation of pacemakers, the return of explanted pacemakers to manufacturers for testing and warranty recoupment, and the effect of these practices on the PPS rates now being paid.

3. Types and duration of pacemaker manufacturer warranty coverage, and the implication of these for recoupment of Medicare's cost for equipment and surgery associated with replacing defective pacer devices.

4. Manufacturers' experience with the testing of explanted pacemakers, and the implications of their experience for Medicare.

Page Two
April 19, 1985
Letter to The Honorable Charles A. Bowsher

5. Based upon GAO's study of over 1,000 pacemaker surgeries at 12 hospitals, please identify the extent of errors and defects identified in the database used to construct PPS rates, their relative magnitude, and their effect on present rates.

Thank you for providing me with copies of the GAO Blue Book entitled "Medicare's Policies and Prospective Payment Rates For Cardiac Pacemaker Surgeries Need Review and Revision". In addition, I would appreciate your providing the Committee with ten copies of your testimony by close of business on April 26, 1985, and an additional 100 copies on the morning of April 29, 1985. Your testimony for submission into the record may be whatever length you deem appropriate. We would, however, appreciate your limiting your oral remarks before the Committee to approximately five minutes.

Should you have any questions regarding the hearing, please have your staff contact James Michie or David Schulke of the Committee staff at 224-5364.

Thank you for your continuing cooperation and assistance.

Sincerely,

JOHN HEINZ
Chairman

JH:dsm

UNITED STATES OF AMERICA

Congreſs of the United States

To James Allen Casey, 5620 Southwest 4th Street, Plantation, Fla. 33317

, Greeting:

Pursuant *to lawful authority, YOU ARE HEREBY COMMANDED to appear before the* Special *Committee on* Aging *of the Senate of the United States, on* May 10*, 19*85*, at* 9:00 *o'clock* a.*m., at their committee room* 628, Dirksen Senate Office Building, Washington, D.C. 20510*, then and there to testify what you may know relative to the subject matters under consideration by said committee.*

FDA investigations of the Cordis Corporation, Miami, Fla., which commenced in 1983 and have continued to the present.

Hereof fail not, *as you will answer your default under the pains and penalties in such cases made and provided.*

To any Committee staff member *to serve and return.*

Given *under my hand, by order of the committee, this* 25th *day of* April*, in the year of our Lord one thousand nine hundred and* eighty-five

Chairman, Committee on Aging

April 30, 1985

I made service of the within subpena

by handing it to

the within-named James

Allen Lacy, at

SDG - 33

Dirksen Senate

Office Building

at 9:45 o'clock a.m., on

the 30th day

of April, 19

Terri Fay Parker

UNITED STATES OF AMERICA

Congress of the United States

To Victor Spanioli, 7315 Southwest 34th Street Road,
Miami, Fla., 33155

, **Greeting:**

Pursuant *to lawful authority, YOU ARE HEREBY COMMANDED to appear before the* Special *Committee on* Aging *of the Senate of the United States, on* May 10 *, 19*85*, at* 9:00 *o'clock* a.*m., at their committee room* 628, Dirksen Senate Office Building, Washington, D.C. 20510*, then and there to testify what you may know relative to the subject matters under consideration by said committee.*

FDA investigations of the Cordis Corporation, Miami, Fla., which commenced in 1983 and have continued to the present.

Hereof fail not*, as you will answer your default under the pains and penalties in such cases made and provided.*

To any Committee staff member *to serve and return.*

Given *under my hand, by order of the committee, this* 25th *day of* April*, in the year of our Lord one thousand nine hundred and* eighty-five.

Chairman, Committee on Aging

April 30, 1925

I made service of the within subpena

by handing it to

Victor [illegible]

the within-named

, at

526-33 [illegible]

Senate Office Bldg

at 9:45 *o'clock* a *m., on*

the 30th *day*

of April*, 19*25

JOHN HEINZ, PENNSYLVANIA, CHAIRMAN
WILLIAM S. COHEN, MAINE
LARRY PRESSLER, SOUTH DAKOTA
CHARLES E. GRASSLEY, IOWA
PETE WILSON, CALIFORNIA
JOHN W. WARNER, VIRGINIA
DANIEL J. EVANS, WASHINGTON
JEREMIAH DENTON, ALABAMA
DON NICKLES, OKLAHOMA
PAULA HAWKINS, FLORIDA
JOHN GLENN, OHIO
LAWTON CHILES, FLORIDA
JOHN MELCHER, MONTANA
DAVID PRYOR, ARKANSAS
BILL BRADLEY, NEW JERSEY
QUENTIN N. BURDICK, NORTH DAKOTA
CHRISTOPHER J. DODD, CONNECTICUT
J. BENNETT JOHNSTON, LOUISIANA
JEFF BINGAMAN, NEW MEXICO
STEPHEN R. McCONNELL, STAFF DIRECTOR
DIANE LIFSEY, MINORITY STAFF DIRECTOR

United States Senate
SPECIAL COMMITTEE ON AGING
WASHINGTON, DC 20510

April 26, 1985

Brendan R. Phibbs, M.D.
Skyline #11
South Parth Route
Jackson, Wyoming 83001

Dear Dr. Phibbs:

As Chairman of the Special Committee on Aging, I am requesting that you appear before the Committee on the morning of May 10, 1985 to testify on the relationship of governmental policies to present patterns of utilization of cardiac pacemakers and associated devices.

As you know, I authored amendments to the Deficit Reduction Act which provided for the establishment of a National Pacemaker Registry, and mandated studies on Medicare reimbursement of physicians and hospitals for pacemaker surgery. The Prospective Payment Assessment Commission (ProPAC) completed its report on Part A reimbursement by the statutory deadline of March 1st. I have enclosed a copy of ProPAC's report for your review and comment. HCFA has missed its March 1st deadline for reporting on the adequacy and appropriateness of physician reimbursement, and now anticipates completing its review by August.

The National Pacemaker Registry was to be established by January 1, 1985, and would contain data on all pacemaker implants and reimplants, as well as pacemaker warranty information. The Registry was designed to protect Medicare beneficiaries from defective pacemakers and unnecessary pacemaker reimplants, as well as providing Medicare with recoupment on defective pacemakers that fail while still under warranty. Committee inquiries indicate, however, that establishment of the Registry itself and promulgation of the regulations required for its operation and maintenance are experiencing lengthy delays.

This hearing will update the Committee's 1982 investigation, with which you were involved, by examining the progress made in recent years toward protecting beneficiaries from unnecessary, expensive, and hazardous surgery. In addition, we will seek to determine if problems persist today, despite these advances. I would, therefore, very much appreciate your addressing the following questions in your prepared testimony:

1. Is there any recent evidence of overutilization of cardiac pacemaker surgery, including initial implanting, explanting, and reimplanting of pacemakers?

Page Two
Letter to Dr. Brendan R. Phibbs

2. What is known of the physiological, economic, social and psychological complications of cardiac pacemaker surgery?

3. Is Medicare paying a prudent and reasonable price for the services of surgeons involved in implanting pacemakers?

4. According to a new General Accounting Office report to be released at the hearing, dual chambered pacemakers now account for some 24% of all pacer implants, compared with only 5% in 1981. What are the implications of the rapidly increasing use of this sophisticated device, especially for the Medicare program?

5. I have enclosed for your review a copy of HCFA's guidelines for pacemaker surgery, as developed by the Public Health Service in 1983, and a copy of the New York State Peer Review Organization's pacemaker guidelines. What is your opinion of the efficacy of these guidelines, in light of recent progress toward an improved understanding of appropriate indications for this surgery?

Please provide the Committee with ten copies of your testimony by the close of business on May 3, 1985, and an additional 100 copies by the morning of May 9, 1985. Your testimony for submission into the record may be whatever length you deem appropriate. We would appreciate your limiting your prepared remarks before the Committee, however, to approximately five minutes. The hearing is scheduled for 9:00 a.m. in room 628 of the Dirksen Senate Office Building, in Washington, D.C.

Should you have questions regarding the hearing, please contact David Schulke, James Michie, or Terri Parker of the Committee staff at (202) 224-5364.

Thank you for your continuing cooperation and assistance.

Sincerely,

John

JOHN HEINZ
Chairman

Enclosures
JH:dsm

JOHN HEINZ, PENNSYLVANIA, CHAIRMAN

WILLIAM S. COHEN, MAINE
LARRY PRESSLER, SOUTH DAKOTA
CHARLES E. GRASSLEY, IOWA
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STEPHEN R. McCONNELL, STAFF DIRECTOR
DIANE LIFSEY, MINORITY STAFF DIRECTOR

United States Senate
SPECIAL COMMITTEE ON AGING
WASHINGTON, DC 20510
April 26, 1985

Howard S. Friedman, M.D.
Chief
Cardiology Section
Brooklyn Hospital
121 DeKalb Avenue
Brooklyn, New York 11201

Dear Dr. Friedman:

As Chairman of the Special Committee on Aging, I am requesting your assistance in the Committee's present inquiry into the relationship of governmental policies to present patterns of utilization of cardiac pacemakers and associated devices.

Last year, I authored amendments to the Deficit Reduction Act which provided for the establishment of a National Pacemaker Registry, and mandated studies on Medicare Reimbursement of physicians and hospitals for pacemaker surgery. The Prospective Payment Assessment Commission (ProPAC) completed its report on Part A reimbursement by the statutory deadline of March 1st. I have enclosed a copy of ProPAC's report for your review and comment. The Health Care Financing Administration (HCFA), however, has missed its March 1st deadline for reporting on the adequacy and appropriateness of physician reimbursement, and now anticipates completing its review by August.

The National Pacemaker Registry was to be established by January 1, 1985, and would contain data on all pacemaker implants and reimplants, as well as pacemaker warranty information. The Registry was designed to protect Medicare beneficiaries from defective pacemakers and unnecessary pacemaker reimplants, as well as providing Medicare with recoupment on defective pacemakers that fail while still under warranty. Committee inquiries indicate, however, that establishment of the Registry itself and promulgation of the regulations required for its operation and maintenance are experiencing lengthy delays.

This inquiry, which you are being invited to participate in, will update the Committee's 1982 investigation by examining the progress made in recent years toward protecting beneficiaries from unnecessary, expensive, and hazardous surgery. In addition, we will seek to determine if problems persist today, despite these advances. I would, therefore, very much appreciate your written response to the following questions:

1. Is Medicare paying a prudent and reasonable price for the services of surgeons involved in implanting pacemakers?

April 26, 1985
Page Two
Letter to Dr. Howard S. Friedman

2. I have enclosed for your review a copy of HCFA's guidelines for pacemaker surgery, as developed by the Public Health Service in 1983, and a copy of the New York State Peer Review Organization's pacemaker guidelines. What is your opinion of the relative efficacy of these guidelines, both when compared to each other and in light of recent progress toward an improved understanding of appropriate indications for this surgery?

I would very much appreciate your response to these questions by the close of business on May 8, 1985, if possible. Should you have questions regarding this request, or the materials enclosed, please contact David Schulke of the Committee staff at (202) 224-5364.

Thank you for your continuing cooperation and assistance.

Sincerely,

JOHN HEINZ
Chairman

Enclosures
JH:dsm

JOHN HEINZ, PENNSYLVANIA, CHAIRMAN

WILLIAM S. COHEN, MAINE
LARRY PRESSLER, SOUTH DAKOTA
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J. BENNETT JOHNSTON, LOUISIANA
JEFF BINGAMAN, NEW MEXICO

STEPHEN R. McCONNELL, STAFF DIRECTOR
DIANE LIFSEY, MINORITY STAFF DIRECTOR

United States Senate
SPECIAL COMMITTEE ON AGING
WASHINGTON, DC 20510

April 26, 1985

The Honorable Carolyne K. Davis, Ph.D.
Administrator
Health Care Financing Administration
314 G Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Dr. Davis:

I am writing to inform you that the hearing at which you were to provide testimony before the Special Committee on Aging has been rescheduled and will be convened on the morning of May 10, 1985 in room 628, Dirksen Senate Office Building, Washington, D.C. The requests in my April 19, 1985, letter concerning the focus and length of your prepared testimony remain unchanged.

Please provide the Committee with ten copies of your testimony by close of business on May 3, 1985, and an additional 100 copies on the morning of May 9, 1985.

Thank you for your cooperation in this important matter.

Sincerely,

John Heinz

JOHN HEINZ
Chairman

Enclosure
JH:jmm

JOHN HEINZ, PENNSYLVANIA, CHAIRMAN

WILLIAM S. COHEN, MAINE
LARRY PRESSLER, SOUTH DAKOTA
CHARLES E. GRASSLEY, IOWA
PETE WILSON, CALIFORNIA
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STEPHEN R. McCONNELL, STAFF DIRECTOR
DIANE LIFSEY, MINORITY STAFF DIRECTOR

United States Senate
SPECIAL COMMITTEE ON AGING
WASHINGTON, DC 20510

April 26, 1985

Norman R. Weldon, Ph.D.
President
Cordis Corporation
P.O. Box 025700
Miami, Florida 33102

Dear Dr. Weldon:

I am writing to inform you that the hearing at which you were to provide testimony before the Special Committee on Aging has been rescheduled and will be convened on the morning of May 10, 1985 in room 628, Dirksen Senate Office Building, Washington, D.C. The requests in my April 19, 1985, letter concerning the focus and length of your prepared testimony remain unchanged.

Please provide the Committee with ten copies of your testimony by close of business on May 3, 1985, and an additional 100 copies on the morning of May 9, 1985.

Thank you for your cooperation in this important matter.

Sincerely,

John Heinz

JOHN HEINZ
Chairman

Enclosure
JH:jmm

JOHN HEINZ, PENNSYLVANIA, CHAIRMAN

WILLIAM S. COHEN, MAINE
LARRY PRESSLER, SOUTH DAKOTA
CHARLES E. GRASSLEY, IOWA
PETE WILSON, CALIFORNIA
JOHN W. WARNER, VIRGINIA
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JEFF BINGAMAN, NEW MEXICO

STEPHEN R. McCONNELL, STAFF DIRECTOR
DIANE LIFSEY, MINORITY STAFF DIRECTOR

United States Senate
SPECIAL COMMITTEE ON AGING
WASHINGTON, DC 20510

April 26, 1985

The Honorable Frank Young, M.D.
Commissioner, Food and Drug Administration
Department of Health and Human Services
5600 Fishers Lane
Rockville, Maryland 20857

Dear Dr. Young:

I am writing to inform you that the hearing at which you were to provide testimony before the Special Committee on Aging has been rescheduled and will be convened on the morning of May 10, 1985 in room 628, Dirksen Senate Office Building, Washington, D.C. The requests in my April 19, 1985, letter concerning the focus and length of your prepared testimony remain unchanged.

Please provide the Committee with ten copies of your testimony by close of business on May 3, 1985, and an additional 100 copies on the morning of May 9, 1985.

Thank you for your cooperation in this important matter.

Sincerely,

JOHN HEINZ
Chairman

Enclosure
JH:jmm

JOHN HEINZ, PENNSYLVANIA, CHAIRMAN

WILLIAM S. COHEN, MAINE
LARRY PRESSLER, SOUTH DAKOTA
CHARLES E. GRASSLEY, IOWA
PETE WILSON, CALIFORNIA
JOHN W. WARNER, VIRGINIA
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STEPHEN R. McCONNELL, STAFF DIRECTOR
DIANE LIFSEY, MINORITY STAFF DIRECTOR

United States Senate
SPECIAL COMMITTEE ON AGING
WASHINGTON, DC 20510

April 26, 1985

The Honorable Charles A. Bowsher
Comptroller General of the United States
U.S. General Accounting Office
Room 7000
441 G Street, N.W.
Washington, D.C. 20548

Dear Mr. Bowsher:

I am writing to inform you that the hearing at which you were to provide testimony before the Special Committee on Aging has been rescheduled and will be convened on the morning of May 10, 1985 in room 628, Dirksen Senate Office Building, Washington, D.C. The requests in my April 19, 1985, letter concerning the focus and length of your prepared testimony remain unchanged.

Please provide the Committee with ten copies of your testimony by close of business on May 3, 1985, and an additional 100 copies on the morning of May 9, 1985.

Thank you for your cooperation in this important matter.

Sincerely,

John Heinz

JOHN HEINZ
Chairman

Enclosure
JH:jmm

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUN 20 1985

The Honorable John Heinz
Chairman, Special Committee on Aging
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

This is in further response to your letter of April 8 regarding your Committee's investigation of medicare/medicaid issues in general and in particular medical devices, many of which are reimbursed under these programs.

We are enclosing additional establishment inspection reports (EIRs), exhibits and miscellaneous memoranda and letters relating to FDA's investigation of the Cordis Corporation. These documents involve an ongoing investigation, and information set forth in the documents could lead to a recommendation for legal action. We are sure you appreciate the need to preserve the integrity of FDA's investigation by maintaining the confidentiality of the documents and will therefore understand that no part of the documents should be disclosed to any member of the public. Also some of the material in the documents is considered confidential information and as such is not releasable to the public under FDA's Freedom of Information regulations.

Some minor deletions have been made because, in our view, the information represents material not releasable outside of the Department under section 301(j) of the Federal Food, Drug, and Cosmetic Act.

If we can be of further assistance, please let us know.

Sincerely yours,

Harry H. [illegible] for
Hugh C. Cannon
Associate Commissioner
for Legislative Affairs

Enclosures

Appendix III

DEPARTMENT OF HEALTH & HUMAN SERVICES Health Care Financing Ad

6325 Security Boulev
Baltimore, MD 21207

Reference: RFP HCFA-84-015
OMB No. 0990-0190
0990-0115

FEB 29 1984

Ladies and Gentlemen:

You are invited to submit a proposal in accordance with the requirements of Request for Proposal (RFP) No. HCFA-84-015 for the Utilization and Quality Control Peer Review Organization (PRO).

Your proposal must be received by the Contracting Officer no later than April 30, 1984, 2:00 p.m. local prevailing time at:

Department of Health and Human Services
Health Care Financing Administration
DPS/Contract Branch - RFP-HCFA-84-015
Room 322, East High Rise Building
6325 Security Boulevard
Baltimore, MD 21207

Special attention is directed to the "Certification of Nonsegregated Facilities" of this solicitation. You are cautioned that failure to agree to the certification shall render your proposal ineligible for award of contracts exceeding $10,000 which are not exempt from the provisions of the Equal Opportunity clause.

Your proposal must be prepared in accordance with the attached "Contract Provisions" and "Instructions to Offerors".

The RFP does not commit the Government to pay any cost for the preparation and submission of a proposal. It is also brought to your attention that the Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with this proposed procurement.

Requests for any information concerning the RFP will be referred only to the undersigned who may be reached on (301) 594-9040 (collect calls will not be accepted). Technical questions must be in writing (See Special Instruction No. 2).

Sincerely yours,

Fredric P. Miller

Fredric P. Miller
Contracting Officer

U.S. Department of Health and Human Services
Health Care Financing Administration

Request For Proposal

RFP NO: HCFA-84-015

OPERATION OF UTILIZATION AND QUALITY CONTROL PEER REVIEW ORGANIZATIONS

(2) Reduce the number of inappropriate or unnecessary admissions or invasive procedures for specific diagnosis related groups (DRGs).

(3) Reduce the number of inappropriate or unnecessary admissions or invasive procedures by specific practitioners or in specific hospitals.

In addition, the contractor shall perform all of the following review activities:

(i) Review, prior to hospital admission (in limited circumstances this may inculde post admission but preprocedure) every elective case proposed for five procedure-related DRGs or DRG groups of those listed in Attachment VII under the heading "Preadmission Review". Review is to be performed in accordance with the preadmission review plan approved by HCFA. An alternate review plan will be approved by HCFA if the offeror can show a greater potential for impact on the utilization or quality of care in the area.

(ii) Review admissions occurring within seven days of a discharge and deny all claims for inappropriate admissions.**

→ (iii) Review every permanent cardiac pacemaker implantation or reimplantation procedure and deny payment for all that are unnecessary.**

→ (iv) For every pacemaker reimplantation, obtain warranty information necessary to identify pacemaker costs reimbursable to Medicare.**

(v) Review transfers from a hospital subject to PPS to either another hospital, or to a PPS-exempt psychiatric, rehabilitation, or alcohol detoxification unit or to a swing-bed within the same hospital, and deny all claims for inappropriate admissions resulting from those transfers.**

(vi) Perform Admission Pattern Monitoring (APM).***

**The Contractor shall perform these activities according to the specifications in Attachment IV to the RFP.

***The Contractor shall perform this activity according to the specifications in Attachment V to the RFP.

[Attachment IV to PRO RFP]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

HEALTH CARE FINANCING ADMINISTRATION

DATE: March 1984

PSRO Transmittal No. 107

To : PSROs
Regional Administrators

From : Administrator

Subject: PSRO Review of Inpatient Hospital Services under the Prospective Payment System (PPS), Transfers From PPS Hospitals, and Admissions within 7 Calendar Days of Discharge From a PPS Hospital

THIS TRANSMITTAL SUPERSEDES PSRO TRANSMITTAL NUMBER 104.

PURPOSE

Title VI of the Social Security Amendments of 1983 (P.L. 98-21) provides that Medicare's payment for Part A hospital inpatient operating costs will be made on a per discharge basis. As a result, some new PSRO review activities will have to be instituted, and some existing activities will need to be modified and strengthened.*

This transmittal replaces PSRO transmittal number 104. The revisions were made based on comments received in relation to PSRO transmittal 104. The substantive changes include:

- correction of the number of diagnosis related groups (DRGs) for which payment can be made (from 467 to 468);
- the addition of review completion requirements;
- clarification of functions which may be delegated;
- the addition of requirements to conduct admission review on cases with specific principal diagnoses identified by the Medicare Code Editor as those which are not indicative of a justified admission;
- revision to the definition of a significant pattern of unnecessary admissions and unnecessary transfers;
- revision to the definition as to when the review of subsets can be substituted for 100% review;
- the addition of requirements to review transfers to an exempt alcohol/drug treatment unit and the addition of corresponding reporting requirements;
- clarification that all cases involving transfers from a PPS hospital to any other acute hospital must be reviewed;
- deletion of the description of the payment methodology for cases involving transfers from a PPS hospital to any other acute hospital;

*The reporting requirements contained in this transmittal require OMB approval under the provisions of the Paperwork Reduction Act. The Health Care Financing Administration is currently seeking such approvals.

thus causing the repeat admission. Perform analysis relevant to stay at first hospital to determine cause(s) and breadth of problem(s).

4. Where an admission was found not to be necessary or appropriate, deny the case and make a recommendation regarding the application of the waiver of liability provision (Section 1879 of the Act) to the intermediary.

5. If the number of unnecessary admissions to a hospital within 7 calendar days of discharge from a PPS hospital divided by the total admissions within seven calendar days of discharge from a PPS hospital reviewed from that hospital is 2.5% or three cases (whichever is greater), review every such case in the following quarter, including those where the 2 stays involve hospitals which are not in the same PSRO area.

6. Institute quality review studies where a problem (e.g., premature discharge) is identified. (See Transmittal Number 100.)

7. Report to the regional office any cases where both admissions are necessary, but where the second stay is as a result of the beneficiary being prematurely discharged from the first stay, summarizing findings. When a pattern of such abuse is identified, develop a sanction recommendation.

II. Invasive Diagnostic and Therapeutic Procedure Review

The performance of invasive diagnostic and therapeutic procedures may affect DRG classifications thus leading to increased reimbursement. Therefore, review all areas involving invasive diagnostic or therapeutic procedures where PSRO data has identified a substantial problem.

→ A. Review every case involving permanent pacemaker insertion using appropriate medical records.

1. When the procedure is found not to meet the PSRO criteria, the physician reviewer/advisor will determine if the procedure was unnecessary. If the procedure is/was found to be unnecessary, deny the procedure and notify the affected parties.

2. If the review is retrospective (i.e., after the pacemaker has been inserted), notify the intermediary so that the DRG can be (re)calculated excluding the procedure.

B. In addition, collect information about permanent pacemaker reimplants.

1. Request from the hospital, the appropriate records to determine the date of the insertion of the replaced and new pacemakers, the name and type of the new and replaced devices, and the warranty period on both devices.

2. If the medical records do not contain sufficient information about the replaced pacemaker, request the appropriate records from the previous admission. If the replaced pacemaker was inserted at another hospital, request the appropriate records only if the hospital is in your PSRO area.

3. Report this information on the report of medical review activity (attached).

C. Identify and review all other invasive procedures where patterns of abuse have been previously identified.

D. In any case reviewed where a procedure was found not to be reasonable or necessary, examine the medical record and determine whether other reasonable and necessary services (beyond routine care) were provided.

1. If such other reasonable and necessary services were not rendered, deny the admission on the grounds that the admission was not reasonable and necessary.

2. If such other reasonable and necessary services were rendered, deny the procedure. (This results in a reasonable and necessary denial of payment for the excluded procedure.)

Notify the intermediary so that the DRG can be (re)calculated and any necessary payment adjustment made.

E. If a pattern of abuse is identified, develop a sanction recommendation.

III. Review of Outliers

A. Day outliers are those cases where the number of covered days in a stay exceeds the average length of stay for discharges in the DRG by a fixed number of days or a fixed number of standard deviations, whichever is the fewer number of days. Day outliers occur automatically at a specified point in time for each DRG.

1. Eligibility for this additional Medicare reimbursement is automatic, and the hospital need not specifically request it.

[Sample PRO Contract Provisions Relating to Required 100% Review of Cardiac Pacemaker Implant, Reimplant, & Warranty]

OMPRO

OREGON MEDICAL PROFESSIONAL REVIEW ORGANIZATION

5210 S.W. Corbett Avenue
Portland, Oregon 97201
(503) 248-1907

April 24, 1984

Frederic P. Miller, Contracting Officer
Department of Health and Human Services
Health Care Financing Administration
DPS/Contract Branch - RFP-HCFA-84-015
Room 322, East High Rise Building
6325 Security Boulevard
Baltimore, Maryland 21207

Dear Mr. Miller:

Enclosed please find the required eight copies of our Technical and Business proposals in response to RFP # HCFA-84-015.

Sincerely,

Faye Gilbarg

Robert A. Berry
Executive Director

Faye W. Gilbarg
Associate Executive Director

enclosures

2.2.2 Pacemaker

OMPRO will review every case involving permanent pacemaker insertion using appropriate medical records. When the procedure is found not to meet the PRO criteria, the physician reviewer will determine if the procedure was unncessary. If the procedure is found to be unnecessary, OMPRO will deny the procedure and notify the affected parties. If the review is retrospective (i.e., after the pacemaker has been inserted), OMPRO will notify the intermediary so that the DRG can be calculated excluding the procedure. OMPRO will also request from the hospital the appropriate records to determine the date of the insertion of the replaced and new pacemakers, the name and type of the new and replaced devices, and the warranty period on both devices. If the medical records do not contain sufficient information about the replaced pacemaker, OMPRO will request the appropriate records from the previous admission. If the replaced pacemaker was inserted at another hospital, OMPRO will request the appropriate records only if the hospital is in Oregon. OMPRO will report this information on the report of medical review activity.

[Sample PRO Contract Provisions Relating to Required 100% Review of Cardiac Pacemaker Implant, Reimplant, & Warranty]

A PROPOSAL TO OPERATE A UTILIZATION AND QUALITY CONTROL PEER REVIEW ORGANIZATION FOR THE STATE OF NEW YORK

Technical Proposal
Volume 1: Chapters 1-6

June 12, 1984

RFP No: HCFA-84-015 (New York)

Submitted to:

Health Care Financing Administration
DPS/Contract Branch
East High Rise Building, Room 389
6325 Security Boulevard
Baltimore, Maryland 21207

Individuals Authorized to Negotiate and Bind the Foundation:

Richard D. Eberle, M.D., President
George B. Pollock, M.D., Vice President
John Q. Podesta, Executive Director (Negotiate Only)
(516) 488-6100

EIN#: 131939109

EMPIRE STATE MEDICAL, SCIENTIFIC AND EDUCATIONAL FOUNDATION, INC.
420 LAKEVILLE ROAD, LAKE SUCCESS N Y 11040

The physicians of the Foundation, again recognizing the obvious need for communication and education, will afford each facility involved the opportunity to meet with physicians to discuss issues raised in this aspect of the review process.

HCFA Required Reports

The PRO Review Activity report will be compiled and submitted within 10 days of the end of the month. The Denials Determination and Sanction Activity Report will be compiled and submitted within 30 days of the end of the quarter.

Task 3: Cardiac Pacemaker and Warranty Review

The Scope of Work includes a requirement to review each cardiac pacemaker implant and reimplant as well as to collect warranty information on reimplant procedures in New York State. There appear to be two factors underlying this specific type of review. In the first place, there are indications that frequently this procedure is performed in instances where it is not medically necessary. Secondly, in the case of reimplantation, hospitals are not actively pursuing recoupment of costs from the device manufacturers when the malfunctioning is covered under terms of a warranty.

In examining this requirement, the physicians of the Foundation have determined that physician education is the best approach to assure impact in this area. To this end, the Foundation will actively distribute and publicize the HCFA Guidelines for Cardiac Pacemaker Insertion to the members of the Statewide medical community. This will be done in conjunction with the Medical Society of the State of New York. By this action, physicians will be placed on notice that one of the conditions or circumstances outlined in these guidelines must be clearly documented or justified in each case for Medicare reimbursement. Further, if a contraindicated condition exists, payment will be denied. In addition, it is intended to disseminate the pacemaker criteia developed by the Inter-society Committee on Heart Diseases. By virture of this review requirement, warranty information will also be gathered in reimplant cases.

It is felt that the scope and purpose of the cardiac pacemaker review requirement addresses the two areas related to potentially unnecessary procedures. The first issue is the reduction of unnecessary procedures by virture of lack of indication. The second, the quality control issue, is related to pacemaker warranties. The Foundation physicians feel confident that their proposal of physician education will decrease the incidence of medically unnecessary pacemaker procedures.

Purpose. The purpose of this review is to determine the medical necessity and appropriateness of every permanent cardiac pacemaker implantation and reimplantation procedure performed on Medicare beneficiaries in acute care hospitals. Additionally, as required by the Scope of Work, warranty information on cases involving reimplantation must also be collected. The Health Care Financing Administration has published guidelines by which the medical necessity for cardiac pacemaker implantation is to be determined and these will be used by the Foundation.

The Foundation is keenly aware of the adverse consequences of denying payment for cardiac pacemaker implantations and reimplantations based on a retrospective medically necessary judgment and lack of such denials will have a potentially adverse effect on the physician/patient relationships. To address the issue and remain in line with the intent of the Scope of Work, the Foundation will conduct a highly structured educational process as is detailed in the "Procedure" section below. The Foundation believes this methodology, accompanied by denials with fiscal impact where deemed appropriate, will serve to impact upon the reduction of unnecessary admissions, an objective of both the PPS and New York waiver systems, and reduce in unnecessary surgery, one of the major quality objectives of the program.

Scope: Review in this category is targeted at 1.5 percent of total Medicare admissions to hospitals in the State. To comply with this requirement, the PRO will conduct nondelegated post payment retrospective review of 100 percent of all cardiac implantation and reimplantations. At the same time, as required by the Scope of Work, warranty information on reimplantation cases will be collected.

[Sample PRO Contract Provisions Relating to Required 100% Review of Cardiac Pacemaker Implant, Reimplant, & Warranty]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE	CONTRACT NO. 500-84-0516	PAGE 1 OF 47 PAGES
NEGOTIATED CONTRACT	NEGOTIATED PURSUANT TO 41 USC 252 (c)(15)	TYPE OF CONTRACT FIRM FIXED PRICE
ISSUING OFFICE Health Care Financing Administration DPS/Contract Branch G-10-A East High Rise Building 6325 Security Boulevard Baltimore, Maryland 21207	CONTRACT FOR "Operation of Utilization and Quality Control Peer Review Organization for the State of Alabama"	
CONTRACTOR (Name and Address) Alabama Quality Assurance Foundation 236 Twin Towers East Birmingham, Alabama 35209	ACCOUNTING AND APPROPRIATION DATA 45998005 2594 7520X8005 961 63-0840366	
PLACE OF PERFORMANCE Birmingham, Alabama	CONTRACT AMOUNT $6,350,000.00	
MAIL VOUCHERS TO See Article XX	SPONSOR Health Standards & Quality Bureau	
	EFFECTIVE DATE July 1, 1984	EXPIRATION DATE June 30, 1986

CONTRACTOR REPRESENTS

1. That it ☐ is, ☒ is not, a small business concern. If he is a small business concern and is not the manufacturer of the supplies to be furnished hereunder, he also represents that all such supplies ☐ will, ☒ will not, be manufactured or produced by a small business concern in the United States, its possessions, or Puerto Rico. (A small business concern for the purpose of Government procurement is a concern, including its affiliates, which is independently owned and operated, is not dominant in the field of operation in which it is contracting and can further qualify under the criteria concerning number of employees, average annual receipts, or other criteria, as prescribed by the Small Business Administration.) (See Code of Federal Regulations, Title 13, Part 121, as amended, which contains detailed definitions and related procedures.)
2. That it is a ☐ REGULAR DEALER IN, ☐ MANUFACTURER OF, the supplies covered by this contract
3. That it is an ☐ INDIVIDUAL, ☐ STATE OR LOCAL AGENCY, ☐ PARTNERSHIP, ☐ JOINT VENTURE, ☒ NON-PROFIT, ☐ EDUCATIONAL INSTITUTION, ☒ CORPORATION organized and existing under the laws of the state of Alabama.

The Contractor agrees to furnish and deliver all supplies and perform all the services set forth in the attached Special Provisions, for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the Special Provisions and the General Provisions. To the extent of any inconsistency between the Special Provisions or the General Provisions and any specifications or other provisions which are made a part of this contract, by reference or otherwise, the Special Provisions and the General Provisions shall control. To the extent of any inconsistency between the Special Provisions and the General Provisions, the Special Provisions shall control.

IN WITNESS WHEREOF, the parties hereto have executed this contract on the day and year last specified below.

Alabama Quality Assurance Foundation NAME OF CONTRACTOR	UNITED STATES OF AMERICA
BY SIGNATURE OF AUTHORIZED INDIVIDUAL	BY William J. Tate SIGNATURE OF CONTRACTING OFFICER
John W. Miller TYPED NAME	William J. Tate TYPED NAME
TITLE Chief Executive Officer	July 10, 1984 DATE
July 10' 1984 DATE	

HEW-684 (7/70)

STATE
PEER REVIEW
ORGANIZATION

ALABAMA QUALITY ASSURANCE FOUNDATION
236 GOODWIN CREST DRIVE, TWIN TOWERS EAST
BIRMINGHAM, ALABAMA 35209
TELEPHONE (205) 942-5440

84 JUN 29 A8:47

June 28, 1984

Health Care Financing Administration
DPS/Contract Branch
Room G-10A
East High Rise Building
6325 Security Boulevard
Baltimore, Maryland 21207

ATTN: Mr. Fredric P. Miller

RE: RFP - HCFA-84-015 (State Of Alabama)

Dear Sir:

Please accept this letter as Amendment #4 to the AQAF Technical Proposal in response to RFP - HCFA-84-015. The changes made in our telephone conversation of June 27, 1984 have been made and are incorporated into the Attachments at tabs.

LIST OF ATTACHMENTS:

1A1-Objective Statement has been reformulated and all baseline data is PSRO 1983 data.

1A2-Objective Statement has been reformulated and all baseline data is PSRO 1983 data.

1A3-Objective Statement has been reformulated and all baseline data is PSRO 1983 data.

1A4-The Objective Statement has been reformulated.

2A -Quality Objective has been revised as recommended.

2B -Quality Objective has been revised as recommended.

2C -Quality Objective has been revised as recommended.

2D -Quality Objective has been revised as recommended.

2E -Quality Objective has been revised as recommended.

Your consideration of the above is greatly appreciated.

Best Regards,

ALABAMA QUALITY ASSURANCE FOUNDATION

John W. Miller
Chief Executive Officer/AQAF

Enclosures
:agw

[RFP QUALITY AREA (4) OBJECTIVE]

ATTACHMENT 2D

OBJECTIVE ON REDUCTION OF UNNECESSARY SURGICAL PROCEDURES (PACEMAKER IMPLANTS)

AMENDMENT #4

I. PROBLEM

Permanent pacemaker implants for medically inappropriate reasons are seen as a national problem. Warranties are seldom taken into consideration at the time of replacement, which could result in a reduction or elimination of replacement cost. A quarterly comparison of implant data for 1982 (568) with 1983 (426) shows a 24% reduction indicating that approximately 20% were medically unnecessary. This baseline is subject to further refinement.

II. OBJECTIVE

By reducing medically unnecessary pacemaker implants, reduce permanent cardiac pacemaker implantations by 10% from 1704 to 1534 (1983 PSRO data) for the first contract year and 20% from 1740 to 1364 (1983 PSRO data) for the second contract year.

III. BACKGROUND

1. The problem of medically unnecessary permanent pacemaker implants are well documented in the literature. Estimates from physicians associated with medical centers across the country estimate 30-50% of all pacemaker implants are unnecessary. ("Fraud, Waste and Abuse in the Medicare Pacemaker Industry;" Special Committee on Aging United States Senate, September 1982, p.1)

2. Kickback, fraud and abuse are reportedly widespread in the industry.

3. Approximately 150,000 people in the United States were projected to receive pacemakers in 1982. Most pacemaker patients are seniors. Implants in patients aged 60-80 account for two-thirds of all implants. ("Fraud, Waste and Abuse in the Medicare Pacemaker Industry;" Special Committee on Aging United States Senate, September 1982, p.1)

4. Around 30% of all pacemaker operations in any given year involve replacement of the device. Most manufacturers offer replacement credit. To the extent replacement

credits are offered for the devices there is no method of tracing compliance and assuring payment to Medicare. ("Fraud, Waste and Abuse in the Medicare Pacemaker Industry;" Special Committee on Aging United States Senate, September 1982, p.1)

5. Based upon 1983 Medicare discharges there were 1,704 permanent pacemaker implantations and 249 replacements in Alabama for that year. Assuring the medical necessity for all permanent pacemaker implants for which DRG payment is made and warranty acountability will provide measurable impact in Alabama.

6. Responding to RFP requirements that permanent cardiac pacemaker implants for Medicare recepients be reviewed at 100% for medical necessity, in October 1983 the Board of Directors of Alabama Medical Review elected to perform the procedure review retrospectively with the aid of a pacemaker reveiw committee comprised of practicing cardiologists. Utilizing DHHS/HCFA guidelines for pacemaker implants, criteria was developed by the committee to extract appropriate diagnoses from records which reflect the need for pacemakers in 100% of the cases. Educational intervention occurred during October 1983 with the forwarding of this screening criteria to hospital administrators and chiefs of staff throughout Alabama.

7. Alabama Medicare discharge data reveals an average of 568 permanent cardiac pacemaker implants and reimplantation procedures per quarter for 1982, as compared to 426 for 1983. This reflects a 24% reduction. Based on the Senate Committee statistics that 30-50% of pacemakers are unnecessary, 100% pacemaker review will continue to show a decrease in the number of permanent cardiac pacemakers for Medicare recepients.

IV. METHODOLOGY

1. Identification of pacemaker implants and replacements will be made utilizing Fiscal Intermediary (FI) reports.

2. Review retrospectively 100% of records against criteria set by the Pacemaker Committee and obtain warranty information in fulfillment of RFP requirements for this mandated review activity. Review will be conducted by reivew supervisors in the Quality Review Department who are trained to read EKGs.

3. Maintain on file data of implant, manufacturer, and warranty information. Forward information quarterly to HCFA.

4. Refer cases not meeting criteria to the Quality Assurance Committee (QAC). When a pacemaker implant is felt unjustified by the QAC, it is then referred to the Pacemaker Committee for review and a final determination.

5. Notification of any Pacemaker Committee denial determination to attending physician and patient.

6. Failure to correct a pattern of inappropriate permanent pacemaker implants will result in referral to the Board of Directors for the following possible action:

   a. any physician whose implants are found to be unnecessary in 10% or more of the cases will be placed on preprocedure certification; or

   b. on retrospective examination of the record following preadmission certification, if any physician continues implants that are not medically necessary, Sanction proceedings will be initiated.

V. MILESTONE CHART

Based upon 1983 PSRO data, the number of permanent pacemaker implantations for 1984-1985 and 1985-1986, the following impact will be measurable:

YEARLY IMPACT

1984-1985 (July-July)

Pacemaker Implants (1983 Baseline):	1704
Decreased by 10%:	170
Total	1534

1985-1986 (July-July)

Pacemaker Implants (1983 Baseline):	1704
Decreased by 20%:	340
Total	1364

QUARTERLY IMPACT

	JUL-SEPT 84	OCT-DEC 84
Quarterly Pacemakers:	426	426
Impact Goal for 10% Reduction:	43	43
Projected Outcome Indicators (Target)	383	383
Activities from Methodology:	1,2,3,4,5	1,2,3,4,5,6

	JAN-MAR 85	APR-JUN 85
Quarterly Pacemakers:	426	426
Impact Goal for 10% Reduction:	43	43
Projected Outcome Indicators (Target)	383	383
Activities from Methodology:	1,2,3,4,5,6	1,2,3,4,5,6

	JUL-SEPT 85*	OCT-DEC 85
Quarterly Pacemakers:	426	426
Impact Goal for 20% Reduction:	85	85
Projected Outcome Indicators (Target)	341	341
Activities from Methodology:	1,2,3,4,5,6	1,2,3,4,5,6

* Sept. 85 (15 mos.)- Projected Pacemakers: 2130 (JUL/84-SEPT/84)
Overall Impact Goal for 12% Reduction: 257
Projected Outcome Indicator (Target): 1873

	JAN-MAR 86	APR-JUN 86
Quarterly Pacemakers:	426	426
Impact Goal for 20% Reduction:	85	85
Projected Outcome Indicators (Target)	341	341
Activities from Methodology:	1,2,3,4,5,6	1,2,3,4,5,6

In the event a physician is found to have a pattern of inappropriate implants, the following schedule will be followed:

1st Month -	Preprocedure review educational intervention and time for correction
2nd Month -	60 days for retrospective review for compliance
3rd Month -	60 days for retrospective review for compliance
4th Month -	Sanction initiated for continued inappropriate implants

VI. MONITORING

Inappropriate implants will be reported monthly to the FI, for DRG reassignment with data analysis for patterns.

[Sample PRO Contract Provisions Relating to Required 100% Review of Cardiac Pacemaker Implant, Reimplant, & Warranty]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE NEGOTIATED CONTRACT	CONTRACT NO. 500-84-0528	PAGE 1 OF 50 PAGES
	NEGOTIATED PURSUANT TO 41 USC 252 (c) (15)	TYPE OF CONTRACT FIRM FIXED PRICE
ISSUING OFFICE Dept. of Health & Human Services Health Care Financing Adminstration 6325 Security Blvd. Rm G-10-A, EHR Baltimore, Maryland 21207	CONTRACT FOR "Operation of Utilization and Quality Control Peer Review Organization for the State of Arizona"	
CONTRACTOR (Name and Address) Health Services Advisory Group, Inc. 301 West Osborn Road, Suite 3800 Phoenix, Arizona 85013	ACCOUNTING AND APPROPRIATION DATA CAN: 45998005 OB CL: 259Y APPRO: 752X8005 ALLOWANCE: 961 EIN: 86-0440007	
PLACE OF PERFORMANCE PHOENIX, ARIZONA	CONTRACT AMOUNT $2,754,127.00	
MAIL VOUCHERS TO SEE ARTICLE XX	SPONSOR Health Standards & Quality Bureau	
	EFFECTIVE DATE August 1, 1984	EXPIRATION DATE July 31, 1986

CONTRACTOR REPRESENTS

1. That it ☒ is, ☐ is not, a small business concern. If he is a small business concern and is not the manufacturer of the supplies to be furnished hereunder, he also represents that all such supplies ☐ will, ☐ will not, be manufactured or produced by a small business concern in the United States, its possessions, or Puerto Rico. (A small business concern for the purpose of Government procurement is a concern, including its affiliates, which is independently owned and operated, is not dominant in the field of operation in which it is contracting and can further qualify under the criteria concerning number of employees, average annual receipts, or other criteria, as prescribed by the Small Business Administration.) (See Code of Federal Regulations, Title 13, Part 121, as amended, which contains detailed definitions and related procedures.)
2. That it is a ☐ REGULAR DEALER IN, ☐ MANUFACTURER OF, the supplies covered by this contract
3. That it is an ☐ INDIVIDUAL, ☐ STATE OR LOCAL AGENCY, ☐ PARTNERSHIP, ☐ JOINT VENTURE, ☒ NON-PROFIT, ☐ EDUCATIONAL INSTITUTION, ☒ CORPORATION organized and existing under the laws of the state of ARIZONA

The Contractor agrees to furnish and deliver all supplies and perform all the services set forth in the attached Special Provisions, for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the Special Provisions and the General Provisions. To the extent of any inconsistency between the Special Provisions or the General Provisions and any specifications or other provisions which are made a part of this contract, by reference or otherwise, the Special Provisions and the General Provisions shall control. To the extent of any inconsistency between the Special Provisions and the General Provisions, the Special Provisions shall control.

IN WITNESS WHEREOF, the parties hereto have executed this contract on the day and year last specified below.

HEALTH SERVICES ADVISORY GROUP, INC. NAME OF CONTRACTOR	UNITED STATES OF AMERICA
BY SIGNATURE OF AUTHORIZED INDIVIDUAL	BY SIGNATURE OF CONTRACTING OFFICER
Ms. Debra L. Nixon, R.N. TYPED NAME	William J. Tate TYPED NAME
TITLE Executive Director	July 30 1984 DATE
July 30, 1984 DATE	

7. If after one quarter, those areas no longer have a 2.5% or three case denial rate, the PRO will resume reviewing invasive diagnostic and therapeutic procedures as outlined in #1 and #2 above.

8. The PRO will collect the following information about permanent pacemaker reimplants: date of insertion of original and new implants, the name and type of the new and replaced devices, and the warranty period on both devices.

HEALTH SERVICES ADVISORY GROUP, INC.

June 8,1984

HCFA
Contract Branch, DPS
Room G-10-A, East High Rise Bldg.
6325 Security Blvd.
Baltimore, Md. 21207
Attn: Donald R. Tabor

Re: RFP No. HCFA-84-01

Dear Mr. Tabor:

Enclosed please find the response to your letter dated May 30, 1984. Health Services Advisory Group, Inc. (H.S.A.G.) has submitted a response to each of the inadequate areas described in your letter.

H.S.A.G. does not anticipate any cost changes relevant to the enclosed revisions or clarifications. If you have any questions regarding the enclosed, please contact me at 602-279-1615.

Received
84 JUN 11 A 8:21

Sincerely,

Debra L. Nixon, R.N.
Executive Director

Enclosures

II. B. 3. Pacemakers review: Page 81A specifies denial of claim if warranty information is not available which is not an issue provided for in PRO guidelines.

H.S.A.G. amends this statement by deleting Attachment I from the review plan. As outlined in our Invasive procedure review, page 97 section II. A., H.S.A.G. will collect information regarding warranty on reimplanted permanant pacemakers, no penalty has been identified by the PRO guidelines if warranty information is not available.

[Sample PRO Contract Provisions Relating to Required 100% Review of Cardiac Pacemaker Implant, Reimplant, & Warranty]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE	CONTRACT NO. 500-84-0535	PAGE 1 OF 57 PAGES
NEGOTIATED CONTRACT	NEGOTIATED PURSUANT TO 41 USC 252(c)(15) and PL 97-248 Subtitle C	TYPE OF CONTRACT Firm Fixed Price
ISSUING OFFICE Dept. of Health and Human Services Health Care Financing Administration 6325 Security Blvd. Room G-10-A EHR Baltimore, Maryland 21207	CONTRACT FOR Operation of Utilization and Quality Control Peer Review Organization for the State of California	
CONTRACTOR (Name and Address) California Medical Review, Inc. 1375 Sutter Street - Suite 402 SanFrancisco, California 94109	ACCOUNTING AND APPROPRIATION DATA 45998005 259Y 7520X8005 961 94-2918600	
PLACE OF PERFORMANCE San Francisco, California	CONTRACT AMOUNT $27,000,000.00	
MAIL VOUCHERS TO See Article XX	SPONSOR Health Standards & Quality Bureau	
	EFFECTIVE DATE Sept. 24, 1984	EXPIRATION DATE See Article V

CONTRACTOR REPRESENTS

1. That it ☐ is, ☒ is not, a small business concern. If he is a small business concern and is not the manufacturer of the supplies to be furnished hereunder, he also represents that all such supplies ☐ will, ☐ will not, be manufactured or produced by a small business concern in the United States, its possessions, or Puerto Rico. (A small business concern for the purpose of Government procurement is a concern, including its affiliates, which is independently owned and operated, is not dominant in the field of operation in which it is contracting and can further qualify under the criteria concerning number of employees, average annual receipts, or other criteria, as prescribed by the Small Business Administration.) (See Code of Federal Regulations, Title 13, Part 121, as amended, which contains detailed definitions and related procedures.)
2. That it is a ☐ REGULAR DEALER IN, ☐ MANUFACTURER OF, the supplies covered by this contract
3. That it is an ☐ INDIVIDUAL, ☐ STATE OR LOCAL AGENCY, ☐ PARTNERSHIP, ☐ JOINT VENTURE, ☒ NON-PROFIT, ☐ EDUCATIONAL INSTITUTION, ☒ CORPORATION organized and existing under the laws of the state of California

The Contractor agrees to furnish and deliver all supplies and perform all the services set forth in the attached Special Provisions, for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the Special Provisions and the General Provisions. To the extent of any inconsistency between the Special Provisions or the General Provisions and any specifications or other provisions which are made a part of this contract, by reference or otherwise, the Special Provisions and the General Provisions shall control. To the extent of any inconsistency between the Special Provisions and the General Provisions, the Special Provisions shall control.

IN WITNESS WHEREOF, the parties hereto have executed this contract on the day and year last specified below.

California Medical Review, Inc. NAME OF CONTRACTOR	UNITED STATES OF AMERICA
BY Jo Ellen Hylind SIGNATURE OF AUTHORIZED INDIVIDUAL	BY William J. Tate SIGNATURE OF CONTRACTING OFFICER
JO ELLEN HYLIND TYPED NAME	William J. Tate TYPED NAME
TITLE Executive Director	September 24, 1984 DATE
Sept 24, 1984 DATE	

HEW-554 (7/70)

(ii) Review admissions occurring within seven days of a discharge and deny all claims for inappropriate admissions.**

(iii) Review every permanent cardiac pacemaker implantation or reimplantation procedure and deny payment for all that are unnecessary.**

(iv) For every pacemaker reimplantation, obtain warranty information necessary to identify pacemaker costs reimbursable to Medicare.**

(v) Review transfers from a hospital subject to PPS to either another hospital, or to a PPS-exempt psychiatric, rehabilitation, or alcohol detoxification unit or to a swing-bed within the same hospital, and deny all claims for inappropriate admissions resulting from those transfers.**

(vi) Perform Admission Pattern Monitoring (APM).***

(vii) Perform admission review according to Section I.A. of Exhibit 1 of this contract.

(viii) Review Medicare admissions to and days of care in specialty hospitals and distinct part psychiatric, alcohol detoxification, and rehabilitation units according to the plan submitted by the contractor in the offer and approved by HCFA.

(ix) Perform review and monitoring of hospital denials in accordance with the specifications in Exhibit 3 of this contract.

b. Quality Objectives

The contractor shall achieve significant improvement in patient care quality. To do so, the contractor shall achieve the outcome-oriented objectives described in Attachment I to Article III. At least one quality objective is required in each of the following areas:

(i) Reduce unnecessary hospital readmissions resulting from substandard care provided during the prior admission.

**The Contractor shall perform these activities according to the specifications in Exhibit 1 to this contract. As modified by Attachment II to Article III.

***The Contractor shall perform this activity according to the specifications in Exhibit 2 to this contract.

Release

CALIFORNIA MEDICAL REVIEW, INC.

RESPONSE TO RFP:HCFA-84-015

TECHNICAL PROPOSAL

TO BECOME THE

MEDICARE UTILIZATION AND QUALITY CONTROL PEER REVIEW ORGANIZATION

JULY 4, 1984

SECTION I

UNDERSTANDING OF WORK

1. SPECIALTY HOSPITAL REVIEW

The PRO is responsible for conducting review in specialty hospitals, even though they are exempt from the prospective payment system. Continued utilization and quality review in these areas are necessary to monitor and correct inappropriate utilization and quality health care patterns.

1) Admission and continued stay review, in addition to quality review studies, are to be conducted at all specialty hospitals. This system is analogous to the PSRO review systems already in place.

2) PRO review of admissions to specialty hospitals permits comprehensive review to take place in all hospitals regardless of which Medicare payment system is in effect.

2. PACEMAKER IMPLANT REVIEW

All procedures involving permanent pacemaker implants will be reviewed for medical necessity of the procedure. This procedure accounts for significant potential misutilization and quality of care problems for the Medicare population.

- All permanent pacemaker implants and reimplants will be reviewed. Data will be collected and reported to HCFA.

- Warranty information on all permanent pacemaker implants will be gathered and forwarded to HCFA to determine manufacturers' financial liability in cases where the devices do not meet warranty specifications. This information will also allow a determination to be made on potential quality of care problems created by ineffective devices.

3. QUALITY OBJECTIVES

Quality objectives comprise a major motivating force in the physician peer review process.

- Maintaining appropriate standards of quality of care is one of the major foundations upon which the American health care systems rests. Quality of care review is a component of all other objectives.

- Monitoring unnecessary hospital admissions, especially those resulting from inappropriate, premature discharges results in an improvement in quality of care. In addition it has a significant impact on unnecessary utilization created in part by the incentives of the prospective payment system.

SECTION II

OBJECTIVES

AND

REVIEW ACTIVITIES

II.A.2.c: Readmission Review (continued)

such case in the following quarter, including those where the two cases involve hospitals which are not in the same PRO area.

The review organization, subsequent to discussion with CMRI, may also elect to incorporate into the quality review objective refering this some topic, a specific diagnostic or procedural focus to correct an identifiable problem.

d) Personnel

Data Staff will analyze any profiles and reports generated by FI, hospital, PRO staff and data system to determine appropriateness of diagnostic admissions and to verify accuracy of hospital reporting.

The review coordinators will analyze the complete medical record applying the above mentioned process (2c) to determine if the readmission was appropriate. The physician advisor will review all questionable cases to determine if the case should be approved or denied, and if the readmission was the result of premature discharge.

Monitoring by CMRI will occur to assure that appropriate mechanisms are in place for patient identification, and for application of review criteria. Corrective actions will be taken by CMRI, consistant with the Monitoring Plan.

→ d. REVIEW OF ALL PERMANENT PACEMAKER INSERTIONS

The PRO will conduct 100% retrospective medical record review of all cases of permanent pacemaker insertions.

1) Description of Problem

Questionable medical indications for insertions of permanent pacemaker insertions have been demonstrated by a recent OMB study. The study produced evidence of inappropriate permanent pacemaker insertions. Medical indications were questionable and it was noted that in some instances the relationship the manufacturer of pacemakers established with cardiologists perhaps precipitated unnecessary insertions. There will also be an incentive for hospitals to encourage pacemaker insertions in order to increase their DRG Reimbursement.

2) Baseline and Projected Measurements

a)

Total HSQB projected discharges:	1,021,830
Total HSQB projected discharges with pacemakers:	15,328
Total HSQB projected rate:	1.5%

b) Data Sources and limitations.
- Scope of Work HSQB projections
- Review activity summary reports

II.A.2.D: Pacemaker Review (continued)

4. Prophylactic pacemaker use following recovery from acute myocardial infarction during which there was temporary complete (third degree) and/or Mobitz Type II second degree AV block.
5. Asymptomatic second degree AV block of Mobitz Type II.
6. Very substantial sinus bradycardia (heart rate less than 45) which is a consequence of long-term necessary drug treatment for which there is no acceptable alternative, when not accompanied by significant symptoms.
7. In patients with recurrent and refractory ventricular tachycardia, "override pacing" (pacing above the basal rate) to prevent ventricular tachycardia.

GROUP III:

Conditions which, although used by some physicians as bases for permanent pacemaker implantation, are considered unsupported by adequate evidence of benefit and therefore should not generally be considered appropriate uses for pacemakers in the absence of indications cited in the above two groups:

1. Syncope of undetermined cause.
2. Sinus bradycardia without significant symptoms.
3. Sino-atrial block or sinus arrest without significant symptoms.
4. Prolonged R-R intervals with atrial fibrillation (without third degree AV block) or with other causes of transient ventricular pause.
5. Bradycardia during sleep.

Unless documentation and development of the case can put a Group III patient into Group I and II, pacemakers for 1 through 5 may be considered inappropriate and should automatically be referred to a physician advisor.

→ e. COLLECTION OF WARRANTY INFORMATION ON PACEMAKER REINSERTIONS

Warranty information (described below) will be collected on all permanent pacemaker implantations, and held on file in the event of a reimplantation in the future.

1) Description of Problem

Potential for replacement of pacemakers that are under warranty. This may indicate defective pacemakers or premature replacement of pacemaker by the physician to potentially increase DRG reimbursement. It is suspected that there is often no financial reimbursement from the manufacturer for defective equipment.

II.A.2.e: Collection of Pacemaker Warranty Info (continued)

2) Baseline and Projected Measurements

a)

Total HSQB projected discharge:	1,021,820
Total HSQB projected discharges with pacemakers:	15,328
Total HSQB projected rate:	1.5%

b) Data sources and limitations.
RFP NO. HCFA-84-015Record

3) Approach to Accomplishing the Activity

The MOU between the PRO and the hospital will state that the hospital medical record is required in the future to contain a copy of the warranty information. The PRO is aware that previously a lack of a uniform procedure for recording warranty information had been used by physicians/providers. This has resulted in some warranty information being retained by the patient, physician's office or the hospital.

PRO will be notified retrospectively through the FI PATbill data system of all pacemaker insertions and provide notice to the review organizations.

Review will be conducted retrospectively, within fifteen (15) calendar days of receipt of record, or within 30 days of initiation of review.

→ Information required to be collected will be:

a. The date of the insertion of the replaced and new pacemakers.
b. The name and the type of the new and replaced device.
c. The warranty period on both devices.

If medical records do not contain sufficient information about the replaced pacemaker, the appropriate records from the previous admission will be requested if in the area designation of the PRO.

In cases when replacements occurred within the warranty period the review will evaluate the indications of replacement. If indications are not present for replacements, the case will be reported to CMRI central office and the regional office via the Monthly Review Activities Summary Report.

Cases in which appropriate replacement is documented will require no further action. Cases where failure of device is noted within warranty will result in notification of FI. Inappropriate replacement within the warranty period of a functioning pacemaker by physician will result in denial of procedure.

If a pattern of abuse is identified, the following actions will be implemented:

II.A.2.e: Collection of Pacemaker Warranty Info (continued)

- Physician education
- Provider notification
- Preprocedure review, using CMRI criteria.

Further pattern of abuse would result in initiation of sanction proceedings.

Monitoring by CMRI will be a part of the monitoring process incorporated in the Plan.

II.A.2.e: Collection of Pacemaker Warranty Info (continued)

Hospital Name:
Hospital Address:
Hospital City/State:

OPERATIVE REPORT

Patient Name:
Patient ID Number:
DATE OF PROCEDURE:
SURGEON:

PREOPERATIVE DIAGNOSIS:
Third degree heart block with severe bradycardia, vertigo and syncope.

POSTOPERATIVE DIAGNOSIS:
Same.

OPERATION:
IMPLANTATION OF A PERMANENT DEMAND PACEMAKER CORDIS MULTICOR II, MODEL NUMBER AND SERIAL NUMBER 402B-12037.

PROCEDURE:
The patient was placed in the dorsal recumbent position on the operating table and the skin of the right chest and neck was prepped with Betadine and sterile drapes applied in the usual manner. Anesthesia was then obtained by local infiltration using 1% Xylocaine. This was done about 2 finger breadths below the right clavicle toward the lateral 1/3. After good anesthesia was obtained, a transverse incision was made in the line of the anesthetized area and carried through the skin and subcutaneous tissue. The dissection was thenc arried up to the cephalic groove where the cephalic vein was identified. It was tied distally with 2-0 TEvdek. A loop of TEvdek was placed around the vein and then the vein was opened and dilated. A transvenous ventricular lead Cordis catalog number 327-152 serial number 1094L was then inserted in the lumen of the vein and followed fluoroscopically into the right ventricle. After a good position was obtained, the lead was connected to a Cordis analyzer and this position was found to pace the heart with a stimulating threshold of .5 millaimps, .3 volts, 550 ohms. The r wave, because of the patient's pulse of 27 beats per minute was very difficult to obtain but it was found to be at least 3.0 millivolts or more. This was felt to be in adequate position and therefore, the catheter was tied to the vein in this position and tests were made to make sure the diaphragm was not paced at full cardiac output at this position. The position was found not to pace the diaphragm and therefore, more anesthesia was injected into the anterior chest. But because of the patient's extremely malnourished condition, and absolutely no subcutaneous fat, it was felt to be best to insert the pacemaker generator beneath the pectoralis major muscle on the right.

Patient Name:
SURGEON:
TYPIST'S INITIALS:
Page Number:
DATE:
TIME:

Appendix IV

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care
Financing Administration

OMS
OMTPO1:OSRB

Memorandum

SIGN: TSK
Due: 10/21
BPO-82-1009

(1) ODS
(2) TW

Date OCT 6 1982

From Director
Bureau of Program Policy

Subject Implementing a Secretarial Directive Concerning Pacemakers

cc: OSPi
~~OMS~~
OPA

To Director
Bureau of Program Operations

As you may know, the Secretary established a task force, chaired by the Administrator, which is to examine problems related to the coverage and reimbursement of cardiac pacemakers. Through the Department Executive Secretariat, the Secretary recently requested a report on the activities and plans of that task force. The attached memorandum was prepared in response to that request.

We would appreciate your advice concerning the item entitled, "Edits to Identify Pacemaker Replacements". Although we are particularly interested in your assessment of the feasibility of identifying claims for pacemaker replacements, any other comments you may have about this proposal will be most welcome.

Thank you for your assistance.

Martin [illegible] for
Larry A. Oday

Attachment

DEPARTMENT OF HEALTH & HUMAN SERVICES Financing Administration

Memorandum

Date

From
Carolyne K. Davis, Ph.D.
Administrator
Health Care Financing Administration

Subject
Progress Report on Activities Underway to Implement the Secretary's September 5 Directive Concerning Pacemakers--Your Note of September 23

To
Thomas M. Antone
Deputy Eecutive Secretary
Office of the Secretary

In view of the specific request by Chairman John Heinz of the Senate Special Committee on Aging in his September 14 letter, we are interpreting the Secretary's mandate as encompassing the findings and recommendations in the reports of both the OIG and Chairman Heinz' Committee. We have prepared a response to Chairman Heinz for the Secretary's signature indicating this. The Task Force and the components it represents will, therefore, be looking at the broad range of questions posed by those reports and preparing recommendations for the Secretary's consideration.

Even before the Secretary's directive, activities were underway within HCFA concerning coverage and reimbursement of pacemakers. The following summarizes those activities and the additional ones which have been undertaken or planned since the Task Force was convened.

Limiting Pacemaker Reimbursement

Currently, virtually all direct costs for pacemakers are reimbursed through hospitals on a cost basis. The forthcoming implementation of total inpatient cost limit and rate of increase control provisions should give hospitals sufficient incentive to exercise prudence in procuring such high cost supply items as pacemakers. Our current commitment to move toward a prospective reimbursement system will further enhance hospitals' incentive to procure pacemakers prudently. We believe this approach is perferable to a piecemeal approach of setting cost limits for individual items and services. Nevertheless, we intend to seek OGC advice as to the legality of establishing limits on pacemaker reimbursement under both Parts A and B of Medicare tied either to the GSA price schedule or to VA reimbursement levels. More immediately, we will explore the feasibility of distributing the pertinent Federal Supply Schedule, with discounted prices for selected models of pacemakers, to hospitals, hospital associations and shared service organizations to apprise them of the favorable prices obtained by the Government and to encourage them to seek reduced prices for themselves.

Limiting Reasonable Charges for Medical Devices

Although we understand that physicians purchase only a small portion of the pacemakers purchased in this country, we are planning during this fiscal year to develop a regulation that would authorize limiting the reasonable charge for any medical devices or equipment furnished to patients by a physician, e.g., pacemakers, to the cost the physician incurred in purchasing the device. That regulation may permit payment of a nominal charge for handling and storage of such devices, but at this point, we are not persuaded such a charge should be allowed. This regulation would eliminate any physician mark-up from the reasonable charge for a pacemaker. It would not, however, reduce the reasonable charge below the market price since we have no authority to consider the reasonableness of the components of prices, e.g., costs of research and development, marketing, etc. We believe that the limits this regulation would impose are consistent with the AMA Code of Ethics which states, in effect, that a physician may not profit from items of medical equipment furnished to patients.

Edits to Identify Pacemaker Replacements

We are also exploring the use of payment edits that would automatically identify claims for pacemaker replacement and alert carriers and intermediaries to the need to examine those claims closely to determine both whether warranty credits are available and if replacement is required for medical reasons.

Coverage Guidelines

Early this year, we began preliminary work on developing coverage guidelines on the medical necessity for newer, high technology cardiac pacemakers. This issue was evaluated by the HCFA Physicians Panel and referred to the Public Health Service (PHS) for additional medical advice. In response to the questions raised by the Health Research Group and the Senate Special Committee on Aging, we have expanded the issues under consideration to include several additional items related to the implantation of pacemakers. These joint HCFA/PHS initiatives will deal with three major areas:

1. General medical necessity guidelines for cardiac pacemaker implants. These guidelines will be issued to Medicare Contractors for their use in determining whether a given implant should or should not be covered. The guidelines will also assure a measure of national consistency in the processing of claims for these services.

2. Specific medical necessity guidelines for new, sophisticated pacemakers. This issue, which HCFA had referred to PHS earlier this year, has the potential for achieving significant program savings. The newer models of pacemakers have expanded, high technological features (self-programmability, solid-state memory of prior pacemaker activity, etc.) which may not be medically necessary for all patients who require pacemakers. Since these devices cost two to three times as much as standard models, limiting implants to only those patients who medically require them should result in substantial long-term savings.

3. Post-implant monitoring of pacemakers. The current guidelines for pacemaker monitoring are interim ones which were adopted in 1980 and were scheduled for review when better data on pacemaker failure rates became available. PHS concluded earlier this year that new data will permit a sharpening of the specificity of the guidelines. The interim guidelines in 1980 resulted in an estimated $23 million program savings annually, and we anticipate that additional savings can be gained from the scheduled revision.

In undertaking these initiatives, HCFA and the PHS will be working together closely to assure maximum coordination and pooling of resources. Both agencies are mindful of the need for timely action and will expedite each of the steps required to prepare and issue expanded contractor guidelines. We have also taken steps to assure close coordination with medical specialty societies, such as the American College of Cardiology, in order to draw upon their advice and expertise and to be fully appraised of new developments in the field. Our target date for developing and publishing revised guideines is January 1, 1983.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care
Financing Administration

Memorandum

Refer to: BPO-S422

Date OCT 26 1982

From **Bureau of Program Operations**

Subject **Edits to Identify Pacemaker Replacements (Your Memorandum of October 6, 1982)—INFORMATION**

To **Bureau of Program Policy**

We feel that claims for pacemaker replacements could easily be identified for closer review. Both intermediary and carrier billing forms contain fields where surgical procedures are to be entered. Since pacemaker replacements always require a surgical procedure, they could be easily identified.

We do not know to what extent intermediaries and carriers may already be examining pacemaker claims. We would be happy to work with you as needed in developing any necessary procedures.

If you have any questions regarding this subject, please contact Stuart Barranco on extension 4-9137.

Dennis Siebert
Acting Director

BPO-S422:SBarranco:smf 10/20/82

medicare
Carriers Manual
Part 3 - Claims Process

Department of Health
and Human Services

Health Care Financing
Administration

Transmittal No. 968

Date March 1983

NEW MATERIAL	PAGE NO.	REPLACED PAGES
Coverage Issues Appendix Sec. 65-4-65-8	5 pp.	2 pp.

NEW POLICY—EFFECTIVE FOR SERVICES RENDERED ON OR AFTER: March 16, 1983

Section 65-6, Cardiac Pacemakers.—This section has been completely revised, and now includes indications for determining the medical necessity of permanent, implanted cardiac pacemakers under Medicare. This section delineates three groups of conditions for which pacemakers have generally been implanted and establishes coverage indications for each. These indications represent an initial step in a series of proposed revisions to Medicare's coverage of such devices. We expect to revise these instructions as additional information on medical indications for pacemaker implants becomes available. We also intend to add specific medical indications for the coverage of newer, more sophisticated cardiac pacemakers.

The Medicare regulations reference is 42 CFR 405.310(k).

gland and would be covered as a prosthetic device in the rare case when it is used in the treatment of "dry eye."

Cross-refer: HCFA-Pub. 13-3, SS 3110.4, 3110.5; HCFA-Pub. 14-3, SS 2130, 2133;
HCFA-Pub. 10, SS 210.4, 211

65-4. CAROTID SINUS NERVE STIMULATOR

Implantation of the carotid sinus nerve stimulator is indicated for relief of angina pectoris in carefully selected patients who are refractory to medical therapy and who after undergoing coronary angiography study either are poor candidates for or refuse to have coronary bypass surgery. In such cases, Medicare reimbursement may be made for this device and for the related services required for its implantation.

However, the use of the carotid sinus nerve stimulator in the treatment of paroxysmal supraventricular tachycardia is considered investigational and is not in common use by the medical community. The device and related services in such cases cannot be considered as reasonable and necessary for the treatment of an illness or injury or to improve the functioning of a malformed body member as required by S 1862(a)(1) of the law.

Cross-refer: HCFA-Pub. 13-3,S 3110.4; HCFA-Pub. 14-3, S 2130; HCFA-Pub. 10, SS 210.4, 211

65-5 ELECTRONIC SPEECH AIDS

Electronic speech aids are covered under Part B as prosthetic devices when the patient has had a laryngectomy or his larynx is permanently inoperative. There are two types of speech aids. One operates by placing a vibrating head against the throat; the other amplifies sound waves through a tube which is inserted into the user's mouth. A patient who has had radical neck surgery and/or extensive radiation to the anterior part of the neck would generally be able to use only the "oral tube" model or one of the more sensitive and more expensive "throat contact" devices.

Cross-refer: HCFA-Pub. 13-3, SS 3110.4; HCFA-Pub. 14-3, S 2130; HCFA-Pub. 10, S 228.4

65-6 CARDIAC PACEMAKERS—EFFECTIVE FOR SERVICES RENDERED ON OR AFTER March 16, 1983

Cardiac pacemakers are covered as prosthetic devices under the Medicare program, subject to the conditions and limitations described in this section. While cardiac pacemakers have been covered under Medicare for many years, to date there have been no specific guidelines for their implantation other than the general Medicare requirement that covered services be reasonable and necessary for the treatment of the condition. Beginning with services rendered on or after the effective date of this instruction all claims for pacemaker implantations are subject to the guidelines of this section.

These guidelines are based on certain assumptions regarding the clinical goals of pacemaker implantation. While some uses of pacemakers represent relatively certain or unambiguous usage, many others require considerable expertise and judgment.

Consequently, the medical necessity for pacemaker implantation must be viewed in the context of the overall management of the particular patient. The appropriateness of such implants may be conditional on other diagnostic or therapeutic modalities having been undertaken. Although significant complications and adverse side effects of pacemakers are relatively rare, they cannot be ignored when considering the use of pacemakers for dubious medical indications, or marginal clinical benefit.

These guidelines represent current medical indications for pacemaker implantation. As with other areas of medicine, advances in knowledge and techniques in cardiology are expected. Consequently, judgments about the medical necessity and acceptability of pacemaker implants can be expected to change. This instruction is, therefore, an initial one, and is expected to be modified as more information becomes available.

It should be noted that this instruction applies only to permanent, implanted pacemakers, and does not address the use of temporary, nonimplanted pacemakers.

The three groups of conditions outlined below deal with the necessity for cardiac pacemaker implants for patients in general. These are intended as guidelines for Medicare contractors to use in assessing the medical necessity of claims for pacemaker implantation. As with other guidelines, final coverage determinations must take account of the circumstances of the particular claim, as well as factors such as the medical history of the individual patient. However, as a general rule, contractors may view the three groups of medical indications below as representing, Group I: conditions under which pacemaker claims may be considered covered without further claims development; Group II: conditions which require more specific claims information, especially evidence of the patient's condition being chronic, rather than episodic, in order to assure coverage; and Group III: conditions which would generally result in denial, unless further claims development shows that they fall into one of the first two categories, or special medical circumstances exist sufficient to convince the contractor that the claim should be paid.

GROUP I: Conditions under which implantation of a cardiac pacemaker is generally considered acceptable or necessary, provided that the conditions are chronic or recurrent and not due to transient causes such as acute myocardial infarction, drug toxicity, or electrolyte imbalance. (In cases where there is a rhythm disturbance, if the rhythm disturbance is chronic or recurrent, a single episode of a symptom such as syncope or seizure is adequate to establish medical necessity.)

1. Acquired complete (also referred to as third degree) AV heart block with symptoms (e.g., syncope, seizures, congestive heart failure, dizziness, confusion or limited exercise tolerance).

2. Congenital complete heart block with severe bradycardia (in relation to age), or significant physiological deficits or significant symptoms due to the bradycardia.

3. Second degree AV heart block (also referred to as AV block and heart block) of Mobitz Type II with symptoms attributable to intermittent complete heart block.

4. Second degree AV heart block of Mobitz Type I with significant symptoms due to hemodynamic instability associated with the heart block.

5. Sinus bradycardia associated with major symptoms (e.g., syncope, seizures, congestive heart failure); or substantial sinus bradycardia (heart rate less than 50) associated with dizziness or confusion. The correlation between symptoms and bradycardia must be documented, or the symptoms must be clearly attributable to the bradycardia rather than to some other cause.

6. In selected and few patients, sinus bradycardia of lesser severity (heart rate 50-59) with dizziness or confusion. The correlation between symptoms and bradycardia must be documented, or the symptoms must be clearly attributable to the bradycardia rather than to some other cause.

7. Sinus bradycardia which is the consequence of long-term necessary drug treatment for which there is no acceptable alternative, when accompanied by significant symptoms (e.g., syncope, seizures, congestive heart failure, dizziness or confusion). The correlation between symptoms and bradycardia must be documented, or the symptoms must be clearly attributable to the bradycardia rather than to some other cause.

8. Sinus node dysfunction with or without tachyarrhythmias or AV conduction block—i.e., the bradycardia-tachycardia syndrome, sino-atrial block, sinus arrest—when accompanied by significant symptoms (e.g., syncope, seizures, congestive heart failure, dizziness or confusion).

9. Sinus node dysfunction with or without symptoms when there are potentially life-threatening ventricular arrhythmias or tachycardia secondary to the bradycardia (e.g., numerous premature ventricular contractions, couplets, runs of premature ventricular contractions, or ventricular tachycardia).

10. Bradycardia associated with supraventricular tachycardia (e.g., atrial fibrillation, atrial flutter, or paroxysmal atrial tachycardia) with high degree AV block which is unresponsive to appropriate pharmacological management and when the bradycardia is associated with significant symptoms (e.g., syncope, seizures, congestive heart failure, dizziness or confusion).

11. The occasional patient with hypersensitive carotid sinus syndrome with syncope due to bradycardia and unresponsive to prophylactic medical measures.

GROUP II: Conditions under which implantation of a cardiac pacemaker may be found acceptable or necessary, provided that the medical history and prognosis of the patient involved can be documented and there is evidence that the pacemaker implantation will assist in the overall management of the patient. As with Group I, the conditions must be present chronically or recurrently, and not due to such transient causes as acute myocardial infarction, drug toxicity, or electrolyte imbalance. Contractors should review claims with a view toward identifying such factors in order to determine whether the particular claims would be covered or not.

1. Acquired complete (third degree) AV heart block without symptoms.

2. Congenital complete heart block of less severe bradycardia (in relation to age).

3. Bifascicular or trifascicular block accompanied by syncope which is attributed to transient complete heart block after other plausible causes of syncope have been reasonably excluded.

4. Prophylactic pacemaker use following recovery from acute myocardial infarction during which there was temporary complete (third degree) and/or Mobitz Type II second degree AV block.

5. Asymptomatic second degree AV block of Mobitz Type II.

6. Very substantial sinus bradycardia (heart rate less than 45) which is a consequence of long-term necessary drug treatment for which there is no acceptable alternative, when not accompanied by significant symptoms.

7. In patients with recurrent and refractory ventricular tachycardia, "overdrive pacing" (pacing above the basal rate) to prevent ventricular tachycardia.

GROUP III: Conditions which, although used by some physicians as bases for permanent pacemaker implantation, are considered unsupported by adequate evidence of benefit and therefore should not generally be considered appropriate uses for pacemakers in the absence of indications cited in the above two groups. Contractors should review claims for pacemakers with Group III indications with a view toward further claims development prior to denying the claim. The contractors should attempt, in further developing the claim, to determine whether the particular claim may actually meet the conditions of Groups I or II. In claims where this is not the case, or where such an event appears unlikely, the contractor may deny the claim.

1. Syncope of undetermined cause.

2. Sinus bradycardia without significant symptoms.

3. Sino-atrial block or sinus arrest without significant symptoms.

4. Prolonged R-R intervals with atrial fibrillation (without third degree AV block) or with other causes of transient ventricular pause.

5 Bradycardia during sleep.

6. Right bundle branch block with left axis deviation (and other forms of fascicular or bundle branch block) without syncope or other symptoms of intermittent AV block.

7. Asymptomatic second degree AV block of Mobitz Type I.

Cross-refer: HCFA Pub. 13-3, §§3101.4,3110.4, HCFA Pub. 14-3, §2130; HCFA Pub. 10, §§210.4, 228.4.

65-7 INTRAOCULAR LENSES (IOL's)

An intraocular lens, or pseudophakos, is a hard artificial lens which may be implanted to replace the natural lens after cataract surgery. Intraocular lens implantation services, as well as the lens itself, may be covered if reasonable and necessary for the individual. Implantation services may include hospital, surgical, and other medical services, including pre-implantation ultrasound (A-scan) eye measurement of one or both eyes.

The Food and Drug Administration (FDA) has classified IOL's into the following four categories, any of which may be covered:

(1) Anterior chamber angle fixation lenses
(2) Iris fixation lenses
(3) Irido-capsular fixation lenses
(4) Posterior chamber lenses

Although the FDA still considers IOL's investigational, their coverage under Medicare is an exception to the general policy not to cover experimental or investigational items or services. The exception is made because the Congress, recognizing the widespread use of IOL's, directed the FDA to study them without interfering with their availability to patients.

Cross-refer: HCFA-Pub. 13-3, §§3110.4, 3151, 3157; HCFA-Pub.14-3, §2130; HCFA-Pub. 10, §228.4

65-8 ELECTRICAL NERVE STIMULATORS

Two general classifications of electrical nerve stimulators are employed to treat chronic intractable pain: peripheral nerve stimulators and central nervous system stimulators.

A. Peripheral Nerve Stimulators.—Payment may be made under the prosthetic devices benefit for the following types of peripheral nerve stimulators:

1. Transcutaneous Electrical Nerve Stimulator (TENS).—This stimulator is attached to the surface of the patient's skin over the peripheral nerve to be stimulated. It may be applied in a variety of settings—in the patient's home, a physician's office, or in an outpatient clinic.

* U.S. GOVERNMENT PRINTING OFFICE: 1983-381-838:286

DEPARTMENT OF HEALTH & HUMAN SERVICES

Financing Administration

Memorandum

Date 14 APR 1983

From Carolyne K. Davis, Ph.D.
Administrator
Health Care Financing Administration

Subject Report to the Secretary on Cardiac Pacemakers

To The Secretary
Through: US________
ES________

Former Secretary Schweiker asked me to chair an intradepartmental task force to examine problems related to the coverage of and reimbursement for cardiac pacemakers. Other members of the Task Force are Dr. Edward Brandt and Dr. Robert Rubin. Mr. Schweiker also requested a report outlining the problems and possible solutions of cardiac pacemaker coverage under Medicare.

We are transmitting with this memorandum the requested report. The report summarizes the issues that have arisen regarding the coverage of and reimbursement for pacemakers and related medical services under Medicare, and the steps the Health Care Financing Administration is taking to deal with them. These activities in association with increased industry and public activities regarding alleged fraud and abuse in the marketing of these devices will go a long way towards assuring that the Medicare program will pay only reasonable amounts for medically necessary services. While the recently published coverage guidelines on the medical necessity for cardiac pacemaker implantation may be interpreted by some physicians as interfering with the practice of medicare and by industry as constraining innovative and technological development, the public reaction to the guidelines has been very positive.

Attachment

Executive Summary

Report to the Secretary on Cardiac Pacemakers

The increasing amount of money being spent for cardiac pacemakers has led to concern with possible inappropriate and excessive use of these devices in the United States. This report concerns the coverage of and reimbursement for cardiac pacemakers under Medicare. The development of technology related to cardiac pacing, while improving the health of heart disease patients (especially the elderly), has led to problems with coverage, reimbursement, and possible overutilization of these devices. This increase in utilization of pacemakers by the Medicare beneficiary population has led to a number of questions concerning medical necessity, cost, and fraud and abuse.

Reports from the HHS Inspector General, the U.S. Senate Special Committee on Aging, and the Nader-affiliated Health Research Group have alleged overutilization of pacemakers under Medicare, and fraud and abuse in the marketing of these devices. These reports have also caused the Senate Finance Committee, as well as individual members of Congress, to express their concern with the possible overutilization and abuse of pacemakers under Medicare. These reports recommend restricting the use of and reimbursement for pacemakers under Medicare. While HCFA is aware of problems with utilization of pacemakers under Medicare, much of the information presented in these reports is anecdotal and may not be an accurate indication of the true nature and extent of the problem.

To address these issues, former Secretary Schweiker established an intradepartmental task force to examine problems related to the coverage of and reimbursement for cardiac pacemakers. As part of this effort, and in recognition of the increasing utilization and cost of pacemakers, HCFA has published, based on the Public Health Service's (PHS) recommendations, coverage guidelines on the medical necessity for implantation of cardiac pacemakers. In addition, HCFA plans to develop guidelines for implantation of the newer, sophisticated pacemakers, and to revise guidelines for post-implant monitoring of pacemakers. HCFA will be implementing the recently enacted prospective payment legislation which contains incentives for hospitals to procure medical devices more prudently. In addition, HCFA will develop a system of claims processing edits which would help contractors ensure that the medical necessity guidelines are followed.

In a December 1982, meeting with HCFA Administrator Carolyne K. Davis, representatives of the pacemaker industry expressed concern that the allegations in the various critical reports on pacemakers not lead to overly restrictive coverage and reimbursement guidelines that would interfere with physicians' judgment. The industry, represented by the Health Industry Manufacturers Association (HIMA), is very much interested in participating in the development of revised coverage and reimbursement guidelines for cardiac pacemakers. The Administrator assured industry representatives that their concerns would be taken into consideration in the development of these guidelines.

Report to the Secretary on Cardiac Pacemakers

The development of the technology related to cardiac pacing has improved the quality of life for hundreds of thousands of heart disease patients, especially the elderly. Because of their contribution toward increasing life expectancy, pacemakers have been implanted in the Medicare beneficiary population in growing numbers. The increase in utilization, combined with rapid advances in pacemaker technology, has led to a number of questions concerning medical necessity and cost. Recent critical attention has also focused on the manufacturing and marketing techniques of pacemaker companies and allegations of overutilization related to marketing, as well as fraud and abuse on the part of the industry. The main sources of criticism are reports prepared by the Public Citizen Health Research Group (a Nader affiliated public concern organization), the Senate Special Committee on Aging, and the HHS Inspector General. Despite the information presented in these reports, the full extent of the problem is not known because of a lack of scientifically valid data.

Since the economic environment in which Medicare functions is one of increasing fiscal restraint, one of HCFA's most pressing challenges is to achieve a balance among several responsibilities. While aiming to meet our administrative responsibility to curb inappropriate expenditures, we also recognize the need to provide adequate health insurance coverage for Medicare beneficiaries in ways that are neutral to the commercial development of new medical procedures and technologies. Moreover, because of the complex nature of the medical and scientific issues involved in cardiac pacing and monitoring, it is necessary to continue our usual practice of seeking medical and scientific advice from experts through the Public Health Service and the private sector. Although this process is still underway, it is apparent that variations in medical and scientific opinion make it difficult to provide precise Medicare guidelines to our contractors on pacemaker utilization and monitoring.

Summary of Suggested Problems and Possible Corrective Steps

Several reports have alleged overutilization of pacemakers under Medicare, and suggest that there have been instances of fraud and abuse in the marketing of pacemakers:

- The Public Citizen Health Research Group (HRG) reports the following:
  - Based on a review of diagnoses for approximately 2,653 Maryland patients receiving pacemakers in 1979 and 1980, the HRG determined that 23 percent of these implants were unnecessary and 13 percent were questionable.
  - Based on these Maryland statistics the HRG estimates that approximately 25 percent of all pacemaker implants are unnecessary, with a yearly cost exceeding $280 million, 75 percent of which is reimbursed by Medicare.
  - The HRG recommends that Medicare take two measures to correct the overutilization of pacemakers:
    1. Require second opinions on the need for a permanent pacemaker as a condition of reimbursement under Medicare.
    2. Require local PSROs to establish criteria for permanent pacemaker insertion and to review all implants done at hospitals under their jurisdiction.

While this report points to a problem with utilization of pacemakers under Medicare, we question the accuracy of the allegations. The information presented appears to be largely anecdotal, and thus may not be an accurate indication of the medical appropriateness of the pacemaker implantation experience to date.

A paper published in the January 1983 issue of the American Journal of Cardiology cites problems with the Health Research Group Report. Drs. Leonard Scherlis and Donald Dembo of the Maryland Society of Cardiology criticized the HRG's use of data extracted from the face sheet of a medical record. Drs. Scherlis and Dembo found that when using these face sheets plus the medical record, numerous errors were found in the HRG study. For example, although coded as having received permanent pacemakers, 16 percent of the patients studied had received temporary devices, battery changes, etc. In addition, diagnoses justifying the insertion of a permanent pacemaker had been omitted in 53 percent of the face sheets, while coding errors were found in 39 percent. According to Drs. Scherlis and Dembo, their findings indicate the difficulties which arise in attempting to justify pacemaker implantation from limited information such as is provided on the face sheet of a medical record.

Over the past few years, we have received other allegations of unnecessary pacemaker implantation and replacement, but have found it extremely difficult to verify their accuracy. Some overutilization may be related to a finding by HCFA's Bureau of Quality Control that from 1976 to 1980 the number of pacemakers implanted by cardiologists decreased, while the number implanted by other practitioners rose. Some believe that the major abuses, to the extent that they exist, result from implants by noncardiologists who are either unfamiliar with the limitations of pacemakers or see these procedures as a source of additional income.

o Office of Inspector General Draft Audit Report - "More Efficient Procurement of Heart Pacemakers Could Result in Medicare Savings of Over $64 Million Annually." This report states that:

  - Approximately 130,000 pacemakers are implanted each year in the U.S. at a cost of $465 million, 80 percent of which is covered by Medicare at prices which significantly exceed those of the Federal Supply Schedule.

  - Fraud and abuse in the manufacturing of pacemakers involves cash kickbacks to physicians, offers of vacations, stock options at reduced prices, and sinecure consulting arrangements. As a result, the report states that the Medicare program pays for these abusive practices through higher-than-necessary prices for pacemakers. The Inspector General believes that savings of $64 million (estimate based on FY 1982 data) are possible if Medicare adopts the prices set by the Federal Supply Schedule for pacemakers, similar to Veterans Administration practice.

  - The IG recommends two ways of limiting reimbursement for pacemakers under Medicare:

    1. Establish prospective limits on the amounts hospitals would be reimbursed for pacemakers.

    2. Conduct demonstration projects on competitive procurement and beneficiary reimbursement under Part B, waiving deductible and coinsurance amounts.

While we agree with the IG's recommendations on prospective limits under Part A for pacemakers and the necessity for more specific coverage guidelines, we believe the other recommendations are not appropriate for the Medicare program. With respect to the IG's recommendation that Medicare develop purchase agreements for pacemakers similar to those used by the VA, we do not believe that all the relevant technical and legal questions were considered. While we are examining the legal, administrative and cost issues involved, we believe that there are several drawbacks to such a demonstration. Nearly all pacemakers are purchased by hospitals, and we do not have the authority to require hospitals to purchase a product competitively. More importantly, the potential HCFA regulation of the methods hospitals use to purchase one of their products is totally inconsistent with the philosophy of prospective payment or of deregulation. We also disagree with the IG's recommendation to conduct experiments and demonstration projects involving limited reimbursement under Part B for pacemakers, because this action would result merely in the transfer of a portion of the cost from the program to the individual beneficiaries, without correcting the real problem of the high cost of pacemakers.

o Report of the U.S. Senate Special Committee on Aging - "Fraud and Abuse in the Medicare Pacemaker Industry."

The Committee is concerned about increasing public reports of excesses in the marketing of cardiac pacemakers, and has made the following observations:

- Excessive cost increases from manufacturers to hospitals are passed on to Medicare and other third-party payors.

- The allegations of overutilization are supported by national comparisons; the U.S. has a utilization rate more that twice that of other free world nations.

- Thirty percent of pacemaker operations per year involve replacement of the device. Even though mechanically failed pacemakers should be covered by the manufacturer's warranty, in many cases the replacement pacemaker is paid for by Medicare, with the manufacturer paying only the remaining uninsured expenses not paid by Medicare and other third party payors. Thus, according to the report, the manufacturers have passed their product liability responsibility on to Medicare. To the extent that warranties are honored, there is no method of tracking compliance and assuring Medicare does not overpay.

- The Committee believes that the frequency schedules and payment rates established by Medicare for followup and monitoring of pacemaker performance are generous. Since pacemaker manufacturers provide the essential equipment, train personnel and provide guidance free of charge on billing Medicare, there is little cost to the physician or clinic. Thus, with reimbursement of 80 percent of approximately $28 to $60 per monitoring, pacemaker monitoring is a very lucrative business.

- Due to excessive profits, the essential comparability of the product, and the tremendous competition within the industry, "creative marketing" strategies have surfaced. These unethical practices include kickbacks, rebates, vacations, gambling junkets, expensive gifts, stock offered as rewards for consulting arrangements, etc.

- The Committee contends that, despite the exposure of these problems and the subsequent investigations that have been generated, these practices continue, due in part to the fragmentation of Federal responsibility and to an absence of leadership within the Department of Health and Human Services.

- The Committee believes that the key to these abuses is found in the symbiotic relationship of physician and pacemaker salesman. While these two individuals are responsible for pacemaker purchase decisions, neither individual has any incentive to be cost-conscious.

HCFA believes that the development of medical necessity guidelines for implantation, replacement and monitoring of pacemakers will encourage physicians and hospitals to be more prudent in their use of pacemakers, thereby addressing the issues of overutilization of pacemakers. In addition, implementation of the recently enacted prospective payment legislation will encourage hospitals to be more cost conscious when purchasing medical devices.

Coverage

Last year HCFA began preliminary work on the development of revised coverage guidelines on the medical necessity for pacemakers, as well as related issues, such as high technology pacemakers, and pacemaker monitoring. The issues were explored by the HCFA Physicians Panel and then referred to the Public Health Service. Based on their advice and recommendations HCFA has recently issued coverage guidelines on the utilization of pacemakers under Medicare.

These guidelines will include:

- Indications for medical necessity of cardiac pacemakers and cardiac pacemaker implants. These guidelines will permit Medicare contractors to determine clearly whether a given implant should or should not be covered and will help ensure a measure of national consistency in the processing of claims for these services.

- Indications for the medical necessity of the newer, sophisticated pacemakers. The newer models of pacemakers have expanded, high technological features (self-programmability, solid-state memory of prior pacemaker activity, etc.) which may not be medically necessary for all patients who require pacemakers. Since these devices cost two to three times as much as standard models, limiting implants to patients who medically require them should result in substantial long-term savings.

- Indications for post-implant monitoring of pacemakers. The current guidelines for pacemaker monitoring are interim instructions, adopted in 1980, and scheduled for review when better data on pacemaker failure rates become available. PHS has stated that data now becoming available will permit a sharpening of the specificity of the guidelines. The interim guidelines in 1980 resulted in an estimated $23 million in program savings annually, and HCFA anticipates that additional savings will be gained from the scheduled revision.

Reimbursement

Congress has recognized in the Tax Equity and Fiscal Responsibility Act (TEFRA) and most recently in the new prospective payment legislation contained in the Social Security Act Amendments of 1983 that the Medicare reimbursement system needs major structural reform to eliminate disincentives, promote efficiency, and thereby reverse the inflationary spiral in hospital expenditures.

The prospective payment legislation will enhance hospital incentives to procure pacemakers prudently. Under the prospective payment system, hospitals would be paid a predetermined rate for each discharge. The rate would be known in advance and there would be no retroactive adjustments made to it. The rate would be different for each type of diagnosis and would be different for various areas of the country. The specific rate per discharge would derive from the average cost per type of discharge utilizing the diagnostic related group (DRG) classification. The payment rate under this system would be based on data currently available to HCFA, specifically a 20 percent sample of bills to beneficiaries (about 2 million bills), and cost reports from each hospital. The prospective payment system will enable us to maintain a commitment to high quality hospital care while taking the necessary steps to establish appropriate economic incentives in the Medicare program and to make the Federal government a prudent buyer of services.

In addition, the prospective payment legislation requires that hospitals provide or arrange for the provision of all services furnished to patients which can be covered under Part A of Medicare so that Medicare's payment to the hospital can be payment in full for all covered items and services, less applicable deductible and copayment amounts. Further, payment for such items and services would be excluded when not provided by or through the hospital.

Operations

In order to identify possible excess billing for pacemakers, HCFA will develop payment edits keyed to pacemaker replacements, to assure proper warranty credits. Such a system of claims processing edits would help ensure that medical necessity guidelines are followed.

- Summary of PHS Recommendations Received to Date:

  The recommendations made by PHS were divided into three major groups of medical indications for implantation of cardiac pacemakers:

  1. Conditions for which the use of permanent cardiac pacemakers are generally medically acceptable, such as severe conduction defects with significant clinical symptoms.

  2. Conditions for which significant numbers of physicians have differing judgments as to medical necessity, such as severe conduction defects without significant clinical symptoms.

  3. Conditions for which pacemakers are not generally supported by accepted medical practice, such as minor conduction defects without clinical symptoms.

The PHS recommendation suggested that their guidelines be used in the way HCFA determines is most appropriate with the understanding that they are valid for the present date and will surely require modification in the future. Thus, the medical necessity guidelines initially developed will be modified as changes occur.

HCFA, will continue to monitor the potential for excessive or abusive payments for pacemakers through ongoing operational reviews. Thus, as the newly developed medical necessity guidelines and the guidelines for the medical necessity of newer, more sophisticated pacemakers and pacemaker monitoring are developed and implemented, the degree to which they are enforced and the effectiveness of operational controls will be evaluated. Ultimately, these reviews would test the effectiveness of contractor and State agency payment sceens and medical review programs. The results of that assessment may lead to consideration of additional program controls such as a second opinion program for pacemaker services and/or the possibility of additional limits on payment for pacemakers.

We are also evaluating the need for in-depth operational reviews of the level of charges for pacemaker implant operations and pacemaker monitoring services. Such a study would focus on the amounts physicians are paid for implanting pacemakers and the amounts Medicare pays for pacemaker monitoring services in light of the innovations in pacemaker technology and surgical procedures that have greatly facilitated both the implant surgery and pacemaker monitoring. In addition, the effects of the implementation of the prospective payment system on the Medicare contractor's ability to prevent excessive or duplicative payment will also be considered for review.

Congressional Interest

On October 4, 1982, HCFA staff met with Senate Finance Committee staff. The Committee's major areas of concern were fraud and abuse, overutilization, and reimbursement for cardiac pacemakers. The Committee staff were informed of HCFA's current activities in developing revised coverage guidelines. While the staff were generally supportive of HCFA's approach, a hearing on this subject may be held early this year.

On November 4, 1982, HCFA staff met with staff of the Senate Select Committee on Aging to discuss coverage of and reimbursement for cardiac pacemakers under Medicare. The staff were specifically interested in bulk purchasing of pacemakers under Medicare, determination of fair price, and warranties, i.e., replacement of faulty pacemakers.

Pacemaker Industry Interest

On December 16, 1982 a meeting was held between HCFA and cardiac pacemaker manufacturers to discuss issues related to Medicare coverage of and reimbursement for cardiac pacemakers. The Administrator briefly reviewed for the industry representatives the various elements which led to the present need for revision of Medicare policies regarding cardiac pacemakers, as well as the activities HCFA has under consideration. Representatives of the pacemaker manufacturers, including the Health Industry Manufacturers Association (HIMA), expressed their concern that HCFA not make significant changes in current policy without adequate input from the industry itself. HCFA representatives emphasized that while open to suggestions from the industry group, there is a need to move quickly to resolve those problems that have been identified. During the meeting, industry representatives were critical of the proposal for bulk purchase of pacemakers, pointing out that some of the data which claim savings for such an approach include both obsolete models and a pricing structure that has since been substantially modified.

Summary of Present and Future Activities

We have issued general medical necessity guidelines for cardiac pacemaker implants in order to assure a measure of national consistency in the coverage and processing of claims for these devices. We are also proceeding with the development of a prospective payment system which will encourage hospitals to procure medical devices prudently.

Future activities include carrier review of pacemaker claims to assure proper warranty credit for faulty pacemakers by establishing payment edits keyed to device replacement, and development of specific medical necessity guidelines for the new, high-technology pacemakers, as well as guidelines for post-implant monitoring of pacemakers.

In undertaking these initiatives, HCFA will be working closely with the Public Health Service to assure maximum coordination and pooling of resources. We have also taken steps to assure close coordination with medical specialty societies, such as the American College of Cardiology, as well as the pacemaker industry itself, in order to draw upon their advice and expertise.

DEPARTMENT OF HEALTH & HUMAN SERVICES Office of the Secretary

Memorandum

Date APR 29 1983

From Claire del Real
Acting Assistant Secretary for Public Affairs

Subject Report to Secretary on Cardiac Pacemakers - Davis 4/14 Memo

To Jackie White
Executive Secretariat

Although the steps taken to date by PHS and HCFA are important ones to combat waste, fraud and abuse in use of cardiac pacemakers, I recommend that the Secretary ask the Task Force for a more specific work plan and timetable for the proposed actions outlined in this report.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Office of the Assistant Secretary
for Health
Washington DC 20201

MAY 9 1983

NOTE TO MARY FRANCES LOWE

Subject: Report to the Secretary on Cardiac Pacemakers - OS# 83041507

I have reviewed the latest report to the Secretary on pacemakers. I do not believe the memorandum of transmittal is strong enough in its emphasis on fraud and abuse in marketing rather than misuse of pacemakers. The report clearly spells out that there is no systematic evidence of misuse, and I recommend that this be clearly stated in the memorandum.

I will be happy to discuss.

E Brandt
Edward N. Brandt, Jr., M.D.

cc: C. Davis/Admin. HCFA

DEPARTMENT OF HEALTH & HUMAN SERVICES
Office of Inspector General

Memorandum

Date MAY 13 1983

From Richard P. Kusserow
Inspector General

Subject Report to the Secretary on Cardiac Pacemakers

To Mary Frances Lowe
Executive Secretariat
Attention: Jackie White

The Office of the Inspector General (OIG) has reviewed the report. We have serious concerns related to the action planned by the Health Care Financing Administration (HCFA) to correct the problems associated with the excessive Medicare reimbursement of cardiac pacemakers.

The U.S. Senate Special Committee on Aging in its report entitled "Fraud and Abuse in the Medicare Pacemaker Industry" documented that Medicare reimbursement for pacemakers is grossly excessive. They also reported that this excessive reimbursement has caused manufacturers, due to competitive pressures, to engage in a variety of unethical practices including kickbacks, rebates, lavish vacations, expensive gifts, free medical equipment, and sinecure contracting arrangements. A subsequent OIG report documented that the excessive reimbursement may be costing Medicare $64 million per year. The Senate report also supported allegations that a large percentage of cardiac pacemaker implants reimbursed by Medicare are not medically necessary.

We believe that the coverage guidelines recently published by HCFA will improve the ability of fiscal intermediaries to make medical review determinations regarding pacemaker implants. We are concerned that HCFA's strategy for correcting problems associated with the reimbursement for pacemakers may mitigate the positive impact of these guidelines. To the extent that reimbursement for pacemakers continues to be excessive, medically unnecessary pacemaker implants will continue to occur.

Page 2 - Mary Frances Lowe

The Health Care Financing Administration believes that the inherent incentives in the prospective payment system will cause providers to be prudent buyers of pacemakers and that the savings will be eventually passed on to the program in the form of reduced payments for pacemaker related DRGs. This appproach will take many years to reduce the excessive amounts paid for pacemakers if, in fact, the strategy works at all. In the meantime, the large scale fraud and abuse will continue.

The OIG believes that prolonging this excessive reimbursement will only subject the Medicare program to increased public and congressional criticism which lends credence to the pervasive perception that Government cannot effectively administer the health care programs. We are aware, for example, that Senator Heinz who conducted the initial pacemaker hearing is still very interested in the area and will likely be displeased with HCFA's approach to resolve the reimbursement problems.

The OIG recommends that HCFA immediately reduce payments for DRGs which involve pacemakers based on the evidence collected by the Congress and OIG that excessive amounts have been paid in the past. This step will add impetus to negotiations between providers and pacemaker suppliers aimed at obtaining price concessions. This will also improve the competitive environment for these negotiations because all providers will be equally committed to obtaining lower prices for pacemakers. To the extent that providers are able to obtain pacemakers at lower prices, excessive reimbursement would not occur and there would be a corresponding decrease in the amounts of kickbacks and other abusive arrangements.

We would appreciate the opportunity to meet with HCFA or the pacemaker task force to discuss our approach in greater detail.

JUL 1 3 1983

NOTE TO JACKIE WHITE

Following are our reactions to Department staff office comments on the Report to the Secretary on Cardiac Pacemakers (attached).

Exec. Sec.

A question was raised by the Department's Exec. Sec. as to why OGC clearance was not obtained for the pacemaker instruction which was issued in March 1983. The reason OGC was not consulted is that no legal issues were involved. The instruction was a revision of an existing instruction that has been in our manuals for a number of years and since the revision raised no new legal issues, OGC clearance was not considered necessary.

Office of ASL(H)

We concur with the Deputy Assistant Secretary for Legislation (Health) that language on the new prospective payment system (PPS) in the pacemaker report gives the mistaken impression that HCFA favors an internal payment limit on pacemakers beyond the DRG rate. We have clarified the report accordingly.

ASPA

The Acting Assistant Secretary for Public Affairs has suggested that we develop a more specific workplan and timetable for the actions proposed in the report. We plan to have the claims processing edits system in place by the end of this fiscal year. With respect to our planned issuance of medical necessity guidelines for the implantation of "high technology" cardiac pacemakers and pacemaker monitoring, we are of course dependent on advice from PHS's Office of Health Technology Assessment. PHS is now considering these matters and will report to us after they have received input from the medical sources with whom they consult outside the agency. We will prepare and issue the guidelines as soon thereafter as possible.

ASH

The Assistant Secretary for Health asked us to emphasize more strongly the fraud and abuse aspect of pacemaker marketing practices in the memorandum of transmittal. We have added language to the transmittal memorandum to do this.

IG

While we fully appreciate the IG's concerns about pacemaker pricing and related abuses, we disagree with his recommendation to reduce DRG's which reflect payment for pacemakers. Our reasons are as follows:

- The recently enacted prospective payment system (PPS) is based on cost data from our present reimbursement system. Under the present system, many costs are reimbursed which, on close scrutiny, could prove to be excessive. Pacemakers are certainly not unique in this regard. We believe Congress viewed PPS as the mechanism with which such excessive costs could be avoided and directed no other payment controls with respect to pacemakers or any other items or services.

- There appears to be no legal basis for altering the 1981 data base upon which DRG's are currently constructed.

- The Actuary indicates there would be problems making program estimates for the types of changes in the PPS that the IG suggests. Such adjustments would represent only minimal changes per DRG amount. In addition, there appears to be no prospect of establishing a reliable, defensible, alternative DRG data base or methodology at this time that would accommodate the IG's concerns.

- In establishing pacemaker-related DRGs, the prospective payment system uses 1981 data which reflects costs for devices that are less sophisticated than the current "state-of-the-art" devices. As pacemakers are improved, the program will continue to pay on the basis of the cost of the 1981 models, with an inflation factor update but not a technical improvement cost update.

- If the IG still believes the program should impose additional limits on pacemaker reimbursement, arrangements can be made for him to meet with the Department's Pacemaker Task Force to discuss the matter.

Kathy Buto

Attachment

Prepared by:BERC:OCP:DMSCP SHippler/SKatz:db 6/23/83
Revised: 6/28/83

DEPAR

V Henry / Bryan
With the warranty info maybe we can cut data for recalibration in 1986. What do you think?
Patricia

Memorandum

JAN 27 1984

Date

Refer to: BPO-P33

From Associate Administrator for Operations

Subject Pacemaker Warranty Recoupment Process (Your Memorandum of January 11, 1984)—INFORMATION

FEB 3

To Associate Administrator for Policy

Assign ORP

This is in response to your memorandum of January 11, 1984. Operations has been attempting to develop a policy for identification and recoupment of pacemaker warranty claims since the early summer of 1983. We have developed a process for identifying and following up with pacemaker manufacturers on possible warranty claims. However, we have been stymied in developing a methodology for actual recoupment of funds because of the implementation of prospective payment for hospital inpatient services.

1. ORPs

We believe the best methodology to identify possible pacemaker warranty claims is through the use of the medical review agent. The Health Care Financing Administration has already mandated 100 percent medical review for implantation and reimplantation of cardiac pacemakers. Inasmuch as the medical review agents will be reviewing reimplants, they will be able to identify possible warranty credits. This will include an identification of the manufacturer and model of pacemaker implanted, as well as the same information for the one removed. A review of the medical record will also allow the medical review agent to obtain the date when the initial implant was performed.

This information will be transmitted to the Medicare intermediary for followup with the manufacturer. The intermediary will maintain a list of pacemaker manufacturer's warranties on specific models. If a credit is available from the manufacturer, the intermediary will be in a position to recoup funds.

hosp's ability to collect on warranty questionable

It is at this point in the process that a modification of the prospective payment regulation appears to be necessary. The intermediary has no direct relation with manufacturers; and, therefore, has no means of reducing payment to the manufacturer. The only alternative is to reduce payment to the hospital that purchased the pacemaker, encouraging it to collect on the warranty claim. The prospective payment regulation does not allow for a reduction to be taken against hospital payment if a warranty claim is available. After discussions with members of the Bureau of Eligibility, Reimbursement and Coverage, it was determined that the prospective payment legislation would allow an offset to be taken against the hospital at the end of the fiscal year for nonrecoupment of warranty claims. However, this will require a change in the January 3, 1984 regulation.

When?

JAN 30 198

I am aware of the promises made to Senator Heinz to ease the pressure for passage of his pacemaker legislation. Nevertheless, I believe it is important to note some of the other difficulties involved in obtaining warranty recoupment, besides revision to the prospective payment regulation. The first problem is that the warranties are under the total control of the manufacturers. If too much pressure is applied to enforce the warranty provisions, the manufacturers will simply drop the warranties, or modify them to make recoupment more difficult.

No law requires warranties

A second possible problem involves the manufacturer's right to examine the removed pacemaker to determine if it was defective. There is a legitimate concern that many of the pacemakers removed will not be proven defective.

The situation then arises in which a physician has implanted a new device that may have not needed to be replaced. The intermediary cannot equitably reduce payment to the hospital when a warranty claim is not honored by the manufacturer. HCFA has no mechanism in place to reduce payment for physician services in this case. Thus, no recoupment will be possible.

Physician's don't like to use same manufacturer's pacemaker once one fails.

I will be happy to discuss this issue further at your convenience.

James L. Scott

medicare
Intermediary Manual
Part 3 - Claims Process

Department of Health
and Human Services

Health Care Financing
Administration

Transmittal No. 1097

Date March 1984

New Material	Page No.	Replaced Pages
Table of Contents Chapter VII	3-174.3--3.174.5 (3pp.)	3-174.3--3-174.4 (2pp.)
Sections 3690-3691	3-247—3-266.2 (26pp.)	3-247—3-262 (16pp.)

→ CLARIFICATION - Effective Date: Not Applicable

Section 3690, Medical Review Under Prospective Payment System (PPS) Diagnosis Related Groups (DRGs) — This section has been revised to indicate that a new payment method will be effective for discharges from a hospital occurring during the hospital's first cost report year beginning on or after October 1, 1983.

Section 3690C was added to institute review completion timeframes.

Section 3690.1, Admission Review -- This section contains numerous revisions as follows:

Section 3690.1A2 has been revised to indicate that at least 5% of admissions must be randomly identified.

Section 3690.1A2c was clarified to show DRG validation.

Section 3690.1A4 has been added to identify cases which require review because the Medicare Code Editor has identified the principal diagnosis as one usually not indicative of a justified admission. This section was also revised to instruct the intermediary to refer these cases to the hospital for PSRO/PRO review where there is a PSRO/PRO in the area.

Sections 3690.1A5 and 3690.1B1e were revised to redefine when the review of subsets can be substituted for 100 percent review.

Sections 3690.1A5, 3690.1B1e and 3690.1D5 were revised to redefine "a significant pattern of unnecessary admissions."

Sections 3690.1A6, 3690.1B1d2, 3690.1B4, 3690.1C2b and 3690.1D6 were revised to clarify reasons for possible sanction action.

Section 3690.1B was clarified to indicate that transfers to exempt units are reviewed.

Sections 3690.1B1d and 3690.1B2b were revised to indicate that diagnostic and procedural information must be validated.

Section 3690.1B3 was added to require the review of transfers to exempt alcohol/drug treatment units.

Section 3690.1B4 has been revised to indicate that where there is a PSRO/PRO in the area, the PSRO/PRO will make all determinations relevant to swing beds.

Section 3690.1C was revised to clarify that all transfers from a PPS hospital to any other acute hospital are reviewed. The explanation of the payment methodology for these transfer cases was deleted.

Section 3690.1D was revised to explain that you do not count the day of discharge, nor the day of admission for admissions within seven calendar days of discharge from an acute facility. This section was also revised to clarify that all claims involving subsequent admissions to any acute hospital (i.e., PPS or non-PPS) within 7 calendar days of discharge from a PPS acute care facility are to be identified.

Section 3690.1D5 was revised to clarify the methodology used to compute the percentage of unnecessary admissions within 7 calendar days of discharge from a PPS hospital.

Section 3690.2, Invasive Diagnostic and Therapeutic Procedure Review -- This section was clarified to indicate that all areas where a pattern of abuse has been found in the past must be reviewed.

Section 3690.2B has been added to explain the procedure for collecting information about permanent pacemaker reimplants.

Section 3690.3, Review of Outliers — This section contains the following revisions.

Section 3690.3A2 was revised to clarify that day outlier claims can be reviewed on a prepayment or postpayment basis.

Section 3690.3A2a was revised to delete the requirement to conduct review prior to adjudication of the day outlier claim. The effect of denied days on DRG and outlier payments was clarified.

Section 3690.3A2d was added to explain that the denial letter should state the total number of days found to be not medically necessary and/or appropriate even though this number might be in excess of the number of days for which excess payment is being sought.

Section 3690.3B2 was revised to clarify that the review of cost outliers will be performed on a prepayment basis.

Section 3690.3B3 was revised to clarify that consideration will be given to the waiver of liability provisions if a cost outlier is denied for medical reasons.

Section 3690.3C was revised to clarify reasons for possible sanction action.

Section 3690.4, DRG Validation -- This section has been revised as follows.

Section 3690.4A was revised to expand the explanation of determinations included in the DRG validation review.

Section 3690.4A1 was revised to indicate that DRG validation reviews are conducted at the hospital site at least once every 3 months. If a hospital had 360 or fewer Medicare discharges for the hospital's last fiscal year, the review can be performed offsite. However, onsite DRG validation must be performed in these hospitals at least once per year.

Section 3690.4A2 was revised to indicate that samples will be selected using Medicare discharges in the "last 3 months". This section was also revised to redefine "a significant pattern of DRG errors" and to change the requirement for increased review when a significant pattern of DRG errors is identified.

Section 3690.4A3 was added to require DRG validation on all cases grouping to DRG 468. This section also includes instructions for the intermediary to refer DRG 468 cases to the PSRO/PRO for review where there is a PSRO/PRO in the area.

Section 3690.4A4 was added to ascertain that the attending physician attested to the diagnoses and procedures used for Medicare billing purposes.

Section 3690.4A5 was added to prohibit the intermediary from notifying the hospital of DRG cases to be reviewed more than 24 hours prior to review and to deny the cases if the medical record cannot be produced.

Section 3690.4B was added to clarify that admission review is performed on each DRG sample case.

Section 3690.4C was revised to clarify that the review described in this section does not need to be performed onsite.

A new section 3690.5 was added to describe the review for excluded items or services.

The section numbers for the previous sections 3690.5 and 3690.6 were revised to 3690.6 and 3690.7, respectively.

Section 3690.6, PSRO/PRO Relationships — This section has been revised to show that the PSRO/PRO must be notified when information submitted by the PSRO/PRO as a result of DRG validation does or does not change the DRG assignment. This section was also revised to stipulate timeframes for providing data to PSROs. The paragraph describing intermediary responsibility where there is a PSRO/PRO performing medical review was moved from this section to Section 3690.5. A description of information which must be included in an intermediary-PSRO/PRO contract or Memorandum of Understanding was added to this section.

Section 3690.7, Report of Medical Review Activities — This section was revised to require monthly reports to be submitted within 10 calendar days of the close of the calendar month. A clarification that the PSRO/PRO relationships section is to be completed for each PSRO/PRO which is performing review was added. This section was also clarified to state that the numbers reported are to reflect completed reviews and that denials reported include those paid under waiver. The addresses for submission of the reports were revised.

The reporting form was revised in the following sections:

- pages 1-6, quarterly reporting was changed to monthly;
- page 1, section 3690.1A, line items were added to collect both the number of admissions sampled/denied and the total admissions reviewed/denied and to report hospital claims processed;
- page 2, line items were added to collect data on transfers to exempt alcohol/drug treatment units;
- pages 3-4, section 3690.2, additional line items were added to collect pacemaker reimplant data;
- pages 4-5, section 3690.3, clarified figures to be reported for day and cost outlier claims;
- pages 5-6, section 3690.4, revised to eliminate duplicative line items, to collect separate statistics on sampled cases, DRG 468 cases, and cases under review for other reasons; and
- page 6, section 3690.6, clarify that the number of DRG errors reported by the PSRO/PRO that resulted in a change in DRG assignment are to be reported in line item 3. Also add a line item to report the PSRO/PRO name and clarify that this section is to be completed for each PSRO/PRO completing medical review in the intermediary area. Added the requirement to collect statistics on DRG 468 cases.

Section 3690.8, Sampling and Universe Review Instructions -- This section was revised to redefine the reject levels and sample sizes.

NEW PROCEDURE — Effective Date: October 1, 1983

Section 3691, Medical Review of Skilled Nursing Facility Admissions From a Prospective Payment System (PPS) Hospital -- Currently, skilled nursing facilities (SNFs) are exempt from reimbursement under the PPS. Therefore, medical review of admissions to SNFs is being strengthened to assure that beneficiaries are not prematurely discharged from PPS acute care facilities and admitted to SNFs. This instruction describes the procedures to be followed in implementing the medical review of admissions to SNFs from PPS hospitals.

In addition, this instruction requires that you complete a Report of SNF Medical Review Activity and submit it within 10 calendar days of the close of the calendar month. This report should only reflect figures on admissions to SNFs from hospitals paid under the PPS.

B. Information on the form HCFA-1453 is currently subject to the Freedom of Information Act (FOIA) and Privacy Act (5 USC Section 552a). To protect "sensitive PSRO/PRO information" from disclosure, any contract or Memorandum of Understanding with the intermediaries to collect and/or process additional required PSRO/PRO data elements shall specify those elements that are PSRO/PRO information and merely being collected and/or processed by the intermediaries.

C. Notify the PSRO/PRO when information submitted by the PSRO/PRO as a result of DRG validation does or does not change the DRG assignment and of the results of changes made by the PSRO/PRO as a result of review of the claims rejected initially by the Medicare Code Editor.

3690.7 Report of Medical Review Activities

Complete and submit within 10 calendar days of the close of the calendar month the following report. (NOTE: Report only those figures reflective of inpatient hospital claims paid under the PPS and only when the medical review authority does not lie with a PSRO/PRO. The numbers submitted should be reflective of completed review efforts. However, complete report about PSRO/PRO relationships as outlined in section 3690.6 for each PSRO/PRO which is performing review.) The denial figures reported should include cases (for admission/transfer review), days/costs (for outlier review), or procedures (for invasive procedure review) which are denied but paid under waiver of liability.

Submit the reports to:

Health Care Financing Administration
Division of Program Operations
Office of Medical Review, HSQB
1849 Gwynn Oak Avenue
Baltimore, MD 21207

In addition, submit a copy of the report to the regional office.

PRO's assumed this responsibility as they were phased in from 7/1/84 - 12/1/84

REPORT OF MEDICAL REVIEW ACTIVITY Page 1 of 7 Pages

Intermediary Number	Month Reporting (M-Y)	
Intermediary Name		
Reporting Section and Item	(Data Entry Identifier)	Number Reporte
Section 3690.1 (A) Admission Review		
HIC numbers used to identify claims for review	(HIC010)	
Number of PPS inpatient hospital claims processed	(AR010)	
Number of PPS inpatient hospital admissions sampled	(AR020)	
Number of denials from sampled admissions	(AR030)	
Total number of PPS inpatient hospital admissions reviewed	(AR040)	
Total number of PPS inpatient hospital admissions denied	(AR050)	
Section 3690.1 (B) Transfers		
HIC numbers used to identify psychiatric transfers	(HIC020)	
Number of inpatient hospital claims involving psychiatric unit transfers	(TR010)	
Number of inpatient hospital claims involving psychiatric unit transfers subjected to medical review	(TR020)	
Number of inpatient hospital claims involving psychiatric unit transfers denied	(TR030)	
Number of inpatient hospital claims involving psychiatric unit transfers referred to the regional office	(TR040)	

REPORT OF MEDICAL REVIEW ACTIVITY Page 2 of 7 Pages

Intermediary Number	Month Reporting (M-Y)	
Intermediary Name		
Reporting Section and Item	(Data Entry Identifiers)	Number Reported
Number of inpatient hospital claims involving rehabilitation unit transfers subjected to medical review	(TR060)	
Number of inpatient hospital claims involving rehabilitation transfers denied	(TR070)	
Number of inpatient hospital claims involving rehabilitation transfers referred to the regional office	(TR080)	
Number of inpatient hospital claims involving alcohol/drug treatment unit transfers subjected to medical review	(TR100)	
Number of inpatient hospital claims involving alcohol/drug treatment transfers denied	(TR110)	
Number of inpatient hospital claims involving alcohol/drug treatment transfers referred to the regional office	(TR120)	
Number of inpatient hospital claims involving swing bed transfers subjected to medical review	(TR140)	
Number of inpatient hospital claims involving swing bed transfers denied	(TR150)	
Number of inpatient hospital claims involving swing bed transfers referred to the regional office	(TR160)	

REPORT OF MEDICAL REVIEW ACTIVITY   Page 3 of 7 Pages

Intermediary Number	Month Reporting (M-Y)	
Intermediary Name		
Reporting Section and Item	(Data Entry Identifier)	Number Report
Section 3690.1 (C) Transfers from a PPS Hospital to Another Hospital		
Number of transfers from a PPS hospital to another hospital	(TO010)	
Number of transfers from a PPS hospital to another hospital denied	(TO020)	
Number of transfers from a PPS hospital to another hospital referred to regional office	(TO030)	
Section 3690.1 (D) Admissions within Seven Calendar Days of Discharge from an Acute Facility		
Number of admissions within seven calendar days of discharge from an acute facility	(AA010)	
Number subjected to medical review	(AA020)	
Number of claims involving admissions within seven calendar days of discharge from an acute facility denied	(AA030)	
Number of claims referred to regional office	(AA040)	
Section 3690.2 Procedure Review		
Number of claims involving pacemaker insertions subjected to medical review	(PR010)	
Number of claims involving pacemaker insertions denied	(PR020)	
Number of permanent pacemaker reimplants	(PR030)	

REPORT OF MEDICAL REVIEW ACTIVITY **Page 4 of 7 Pages**

Intermediary Number	Month Reporting (M-Y)	
Intermediary Name		
Reporting Section and Item	(Data Entry Identifier)	Number Reported
Name and type of new and replaced pacemaker reimplanted (Attach narrative)	(PR040)	
Date of insertion of new and replaced device (Attach narrative)	(PR050)	
Warranty period for new and replaced devices (Attach narrative)	(PR060)	
Number of claims involving other procedures subjected to medical review (Attach narrative)	(PR070)	
Number of claims involving other procedures denied (Attach narrative)	(PR080)	
Number of claims referred to regional offices	(PR090)	
Section 3690.3 Review of Outliers		
Number of day outlier claims	(RO010)	
Number of claims approved in the day outlier category	(RO020)	
Number of days approved as day outliers (report only days exceeding the DRG threshold)	(PR030)	
Number of days denied as day outliers (report denied days up to the amount of days exceeding the DRG threshold)	(PR040)	
Most prevalent DRG approved as day outlier	(PR050)	
Most prevalent DRG denied as day outlier	(PR060)	
Number of claims involving cost outliers (report only cases initially identified as potential cost outliers which have already been reviewed)	(PR070)	

REPORT OF MEDICAL REVIEW ACTIVITY Page 5 of 7 pages

Intermediary Number	Month Reporting (M-Y)	
Intermediary Name		
	(Data Entry Identifier)	Number Reported
Reporting Section and Item		
Number of claims approved as cost outliers	(R0080)	
Amount of money (charges) approved as cost outliers (report only charges exceeding the DRG threshold)	(R0090)	
Amount of money (charges) denied as cost outliers (report denied charges up to the amount exceeding the DRG threshold)	(R0100)	
Most prevalent DRG approved as cost outlier	(R0110)	
Most prevalent DRG denied as cost outlier	(R0120)	
Section 3690.4 DRG Validation		
Number of hospitals visited for DRG validation (Add list of names of hospitals as an attachment to this report)	(DV010)	
Total number of random sample cases reviewed (all hospitals)	(DV020)	
Erroneous DRG Assignments (Random Sample - All Hospitals) (List, in descending order or frequency, along with the number of errors for each. Do not list DRGs with no errors detected. Use extra sheets as necessary.)	(DV030)	
Total number of cases grouping to DRG 468	(DV040)	

REPORT OF MEDICAL REVIEW ACTIVITY Page 6 of 7 pages

Intermediary Number

Month Reporting (M-Y)

Intermediary Name

Reporting Section and Item	(Data Entry Identifier)	Number Reported
Number of DRG 468 cases with:		
- incorrect principal diagnosis	(DV051)	
- incorrect surgical procedures	(DV052)	
- surgical procedure related to principal diagnosis not listed	(DV053)	
- other	(DV054)	
Number of DRG 468 cases with errors that resulted in a change in DRG assignment	(DV055)	
- number that resulted in a higher priced DRG	(DV056)	
- number that resulted in a lower priced DRG	(DV057)	
Number of cases under review for other reasons (all hospitals)	(DV060)	
Erroneous DRG assignments (cases under review for other reasons - all hospitals) (List, in descending order or frequency, along with the number of errors for each. Do not list DRGs with no errors detected. Use extra sheets as necessary.)	(DV070)	
Total number of DRG errors identified (all cases)	(DV080)	
Total number of DRG errors that resulted in a change in DRG assignment (all cases)	(DV090)	
Section 3690.6 PSRO/PRO Relationships (Complete this section for each PSRO/PRO performing medical review in the intermediary area.)		
Name of PSRO/PRO	(PS010)	
Number of DRG errors identified by the PSRO/PRO (Attach narrative)	(PS020)	

REPORT OF MEDICAL REVIEW ACTIVITY Page 7 of 7 page:

Intermediary Number	Month Reporting (M-Y)	
Intermediary Name		
Reporting Section and Item	(Data Entry Identifier)	Numbe Repor
Number of DRG errors identified by the PSRO/PRO that resulted in a change in DRG assignment (Attach narrative)	(PS030)	________
Number of DRG 468 cases with errors that resulted in a change in DRG assignment	(PS031)	________
- number that resulted in a higher priced DRG	(PS032)	________
- number that resulted in a lower priced DRG	(PS033)	________
Value (dollar amounts) of PSRO/PRO DRG adjustments (Attach narrative)	(PS040)	________

BQC

PACEMAKER REPLACEMENTS STUDY

4

STUDY OBJECTIVES

IDENTIFY:

–proportion of replacements to all implants

–reasons for replacements

–patients medical conditions

–sophistication of units of reimplanted

STUDY METHOD

- random sample
- analysis of hospital medical & financial records
- unit of analysis: MEDICARE beneficiaries
- review period: calendar year 1982

SCOPE OF REVIEW

-regions II, IV, V participated (50.1% of implants done
in these 3 regions)

-129 hospital medical & financial records of beneficiaries
who received replacement pacemakers reviewed

30 – Region II
54 – Region IV
45 – Region V

- 10 MEDICARE carriers assisted in sample selection
- 69 hospitals visited
- $1,261,286 : total charges to MEDICARE for 129 cases
- $9,777 : average total charge per replacement operation

CONDUCT OF REVIEW

-all carriers asked to provide pacemaker utilization data for CY 82

-carriers that provided sample data selected based
on pacemaker service volume
(excluded temporaries, leads/electrodes & monitoring)

-samples selected randomly, stratified by carriers,
based on volume

-carriers asked to provide copies of bills for sample cases

-hospitals identified & contacted & data collected

OBJECTIVE:

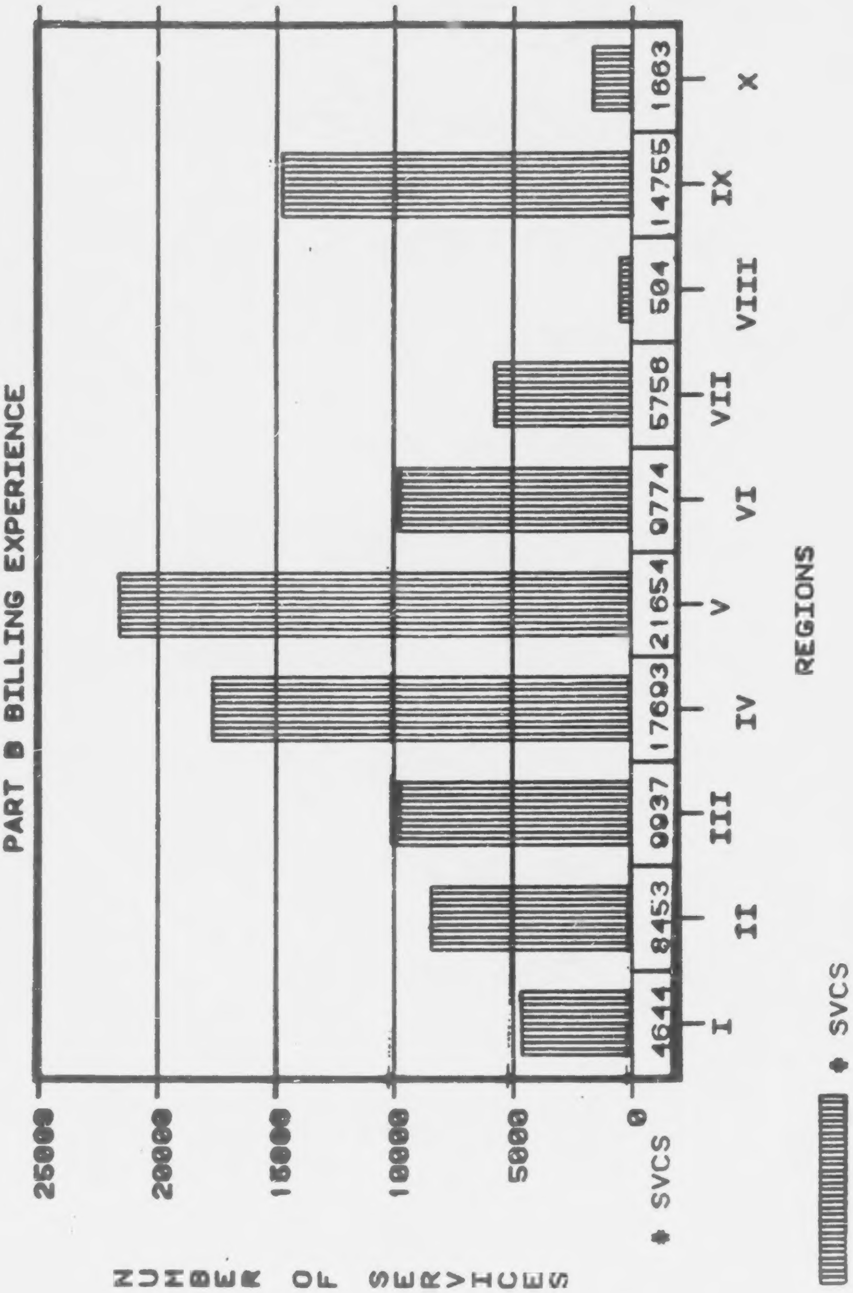
DETERMINE THE PROPORTION
OF IMPLANTS THAT ARE
REPLACEMENTS

approximately 95,000 pacemakers

implanted in MEDICARE beneficiaries in CY 1982

PACEMAKER IMPLANTS IN 1982 (94,833 SVCS)

PART B BILLING EXPERIENCE



—Part B bills for implants fall into 8 categories

BILLING CATEGORIES

A – INSERTION OF PERMANENT PACEMAKER BY
THOROCOTOMY OR XYPHOID APPROACH

B – INSERTION OR REPLACEMENT OF TRANSVENEOUS
ELECTRODES & PACEMAKER

C– INSERTION OF A/V SEQUENTIAL PACEMAKER

D – IMPLANTATION OF SUBCUTANEOUS BATTERY
PACK & ELECTRODES

E – INSERTION OR REPLACEMENT OF PACEMAKER ONLY

F – REPAIR OF PULSE GENERATOR ONLY

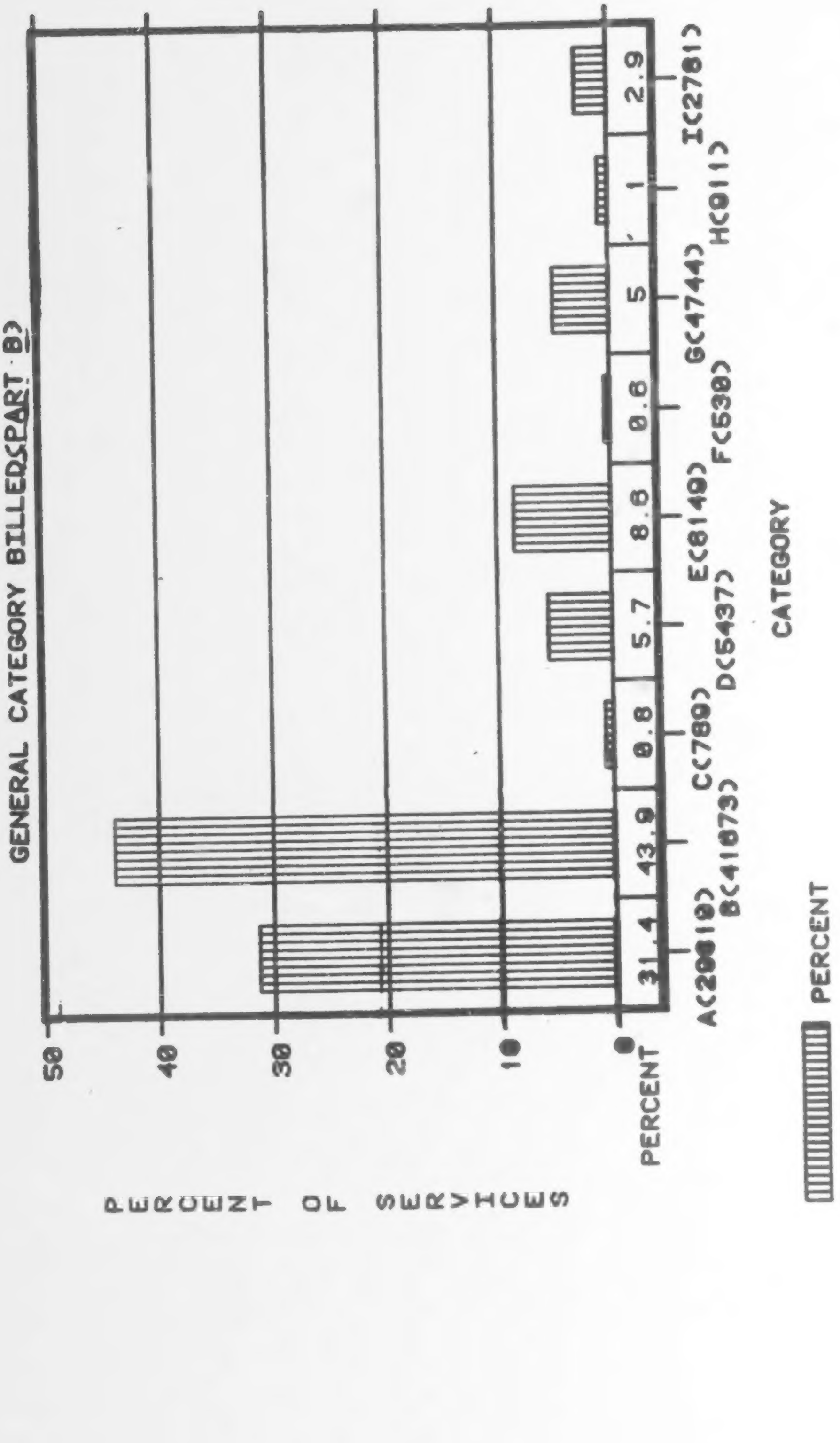
G – REIMPLANTATION OF PACEMAKER

H – INSERT, REPLACE, OR REPAIR PACEMAKER

CATEGORIES F & G ACCOUNT FOR 5.6% OF TOTAL

THE OTHER CATEGORIES ACCOUNT FOR 91.5%

PACEMAKER IMPLANTS BY
GENERAL CATEGORY BILLED(PART B)



BEST ESTIMATE OF PROPORTION OF PACEMAKER
IMPLANTS THAT ARE REPLACEMENTS IS 21%
(from American Heart Association survey of
implanting physicians)

THUS APPROXIMATELY 20,000 REPLACEMENTS IN 1982

$195 million

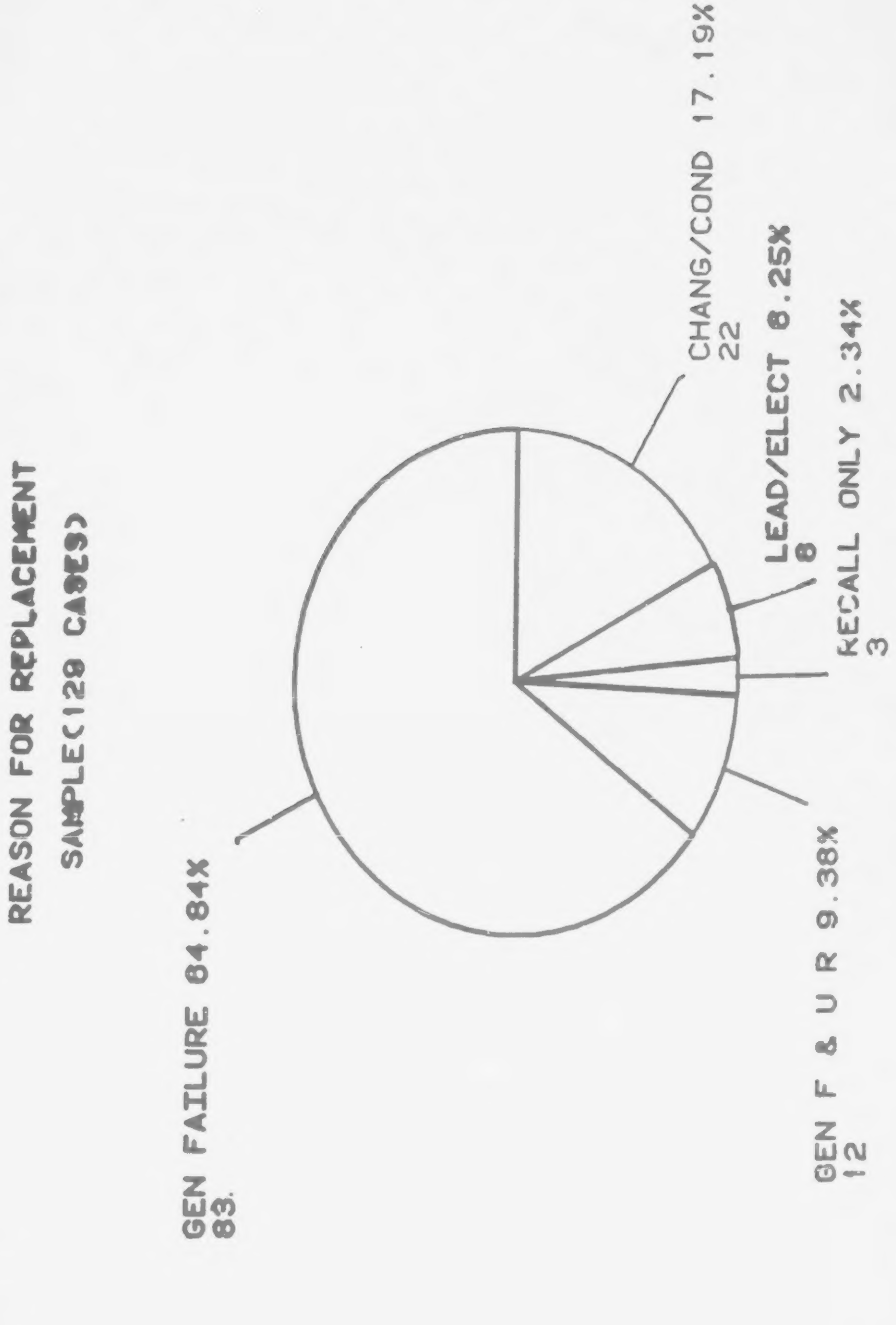
approximate cost to Medicare for replacement of
pacemakers in CY 1982

20,000 replacements
X $9,777 avg cost per replacement
$195 million

SAMPLE DATA

OBJECTIVE :

IDENTIFY THE REASONS FOR REPLACEMENTS


REASON FOR REPLACEMENT
SAMPLE(128 CASES)
GEN FAILURE 64.84% 83
CHANG/COND 17.19% 22
LEAD/ELECT 6.25% 8
RECALL ONLY 2.34% 3
GEN F & U R 9.38% 12

OBJECTIVE :

IDENTIFY PATIENTS PATIENTS' MEDICAL
& DIAGNOSTIC CONDITIONS

(list of individual patient conditions
available on request)

OBJECTIVE :

DETERMINE HOW OFTEN THE REPLACEMENT PACEMAKERS ARE MORE SOPHISTICATED THAN THE UNITS REPLACED.

- compared the ICHD (Inter–Society Commission for Heart Disease) codes of replacement units with the units replaced

ICHD code developed by the 1974 PACEMAKER STUDY GROUP

ICHD code indicates:

CHAMBER PACED		CHAMBER SENSED		MODE OF RESPONSE	
V:	ventrical	V:	ventrical	I:	inhibited
A:	atrium	A:	atrium	T:	triggered
D:	both			O:	n/a

TWO POSITIONS HAVE BEEN ADDED:

PROGRAMMING FUNCTION

P: simple programming
M: multiprogrammability
C: communicating telemetry function

O: no programming

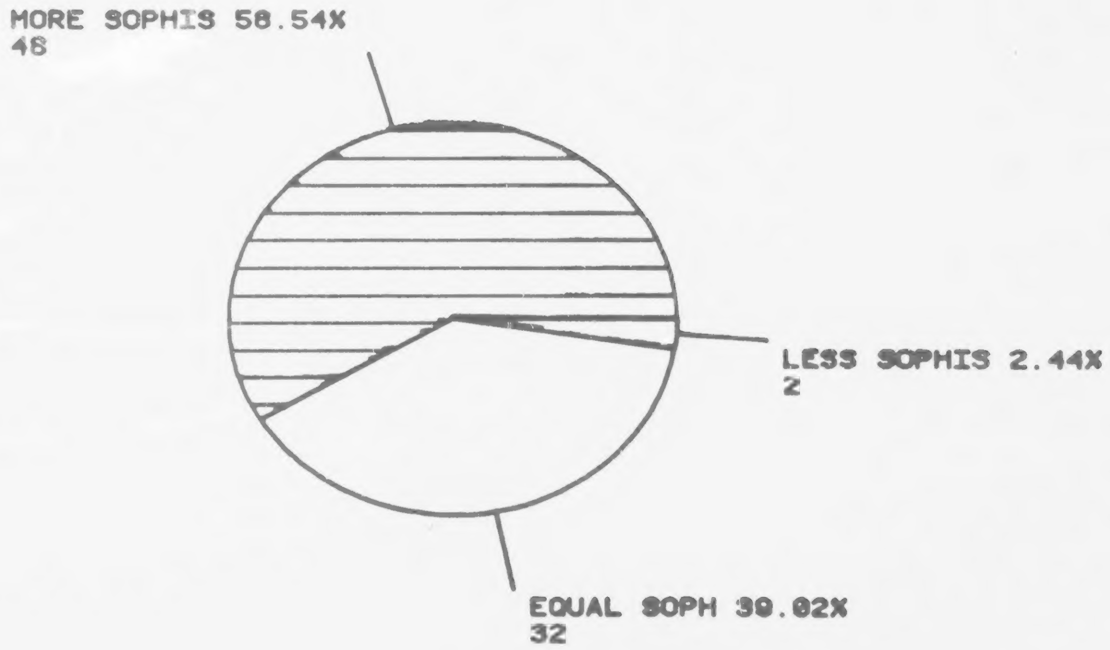
ANTITACHYARRHYTHMIA FEATURES

B: burst of impulses
N: normal rate competition
S: scanning response

E: external control

UNIT SOPHISTICATION

SAMPLE



82 UNITS COMPARED

UNIT SOPHISTICATION

	less	equal	more	sub total	can't tell	total
recalls	0	11	1	12	2	14
warranty	0	9	11	20	1	21
regular	2	12	36	50	44	94
total	2	32	48	82	47	129

PRICE OF REPLACEMENT UNITS TO UNITS REPLACED

The "avg." replacement unit cost approx. $815 more
than the unit replaced

-based on a comparison of the list prices of
63 original & 63 replacement units

-source of prices :
manufacturers' price lists

COST TO HOSPITALS

$3,656—avg. amount hosps. paid for pulse generators

—based on 65 hospital invoices for pulse generators

$4,959

–avg. amount hospitals CHARGED Medicare for replacement units

based on 80 hospital bills

avg. amount hosps. charged Medicare

approx. 35.5% more than their average cost

$$\begin{array}{r} \$4{,}959 \\ \underline{-\$3{,}656} \\ \$1{,}303 \end{array}$$

$\$1{,}303 \div \$3{,}656 = 35.6\%$

RECALLS

16, or 12.3%, of sample cases had been recalled by their manufacturer.

2 cases or 1.6%, contain evidence confirming that the hospital received a gratis pulse generator and/or $ credit from the manufacturer.

14, or 10.9%, no indication of manufacturers' credit or receipt of gratis pulse generator was found.

$ VALUE OF RECALLS

2460 estimated recalls in 1982
(20,000 replacements X 12.3% sample recalls)

$24,600,000 estimated cost to Medicare
(2460 recalls X $10,000 avg. total cost for replacement op.)

$8,993,760 estimated cost of pulse generators
(2460 recalls X $3656 avg. hosp. cost for pulse generators)

2,180	estimated number of cases for which Medicare did not get credit (20,000 replacements X 10.9%)
$21,800,000	estimated cost to Medicare for replacement operations in recall situations (2180 X $10,000)
$7,970,080	estimated value of the pulse generators (2,180 X $3,656)

WARRANTIES

21, or 16.3%, of the sample involves warranties.

3 cases—hospital receipt of a free unit and/or $ credit from the manufacturer was confirmed.

16, or 12% of the cases—no indication that warranties were enforced or honored.

$ VALUE OF WARRANTY SITUATIONS

3260 estimated cases involving warranties
(20,000 replacements X 16.3%)

$32,600,000 estimated cost to Medicare
(3260 recalls X $10,000 avg. total cost for replacement op.)

$11,918,560 estimated cost of pulse generators
(3260 recalls X $3656 avg. hosp. cost for pulse generator)

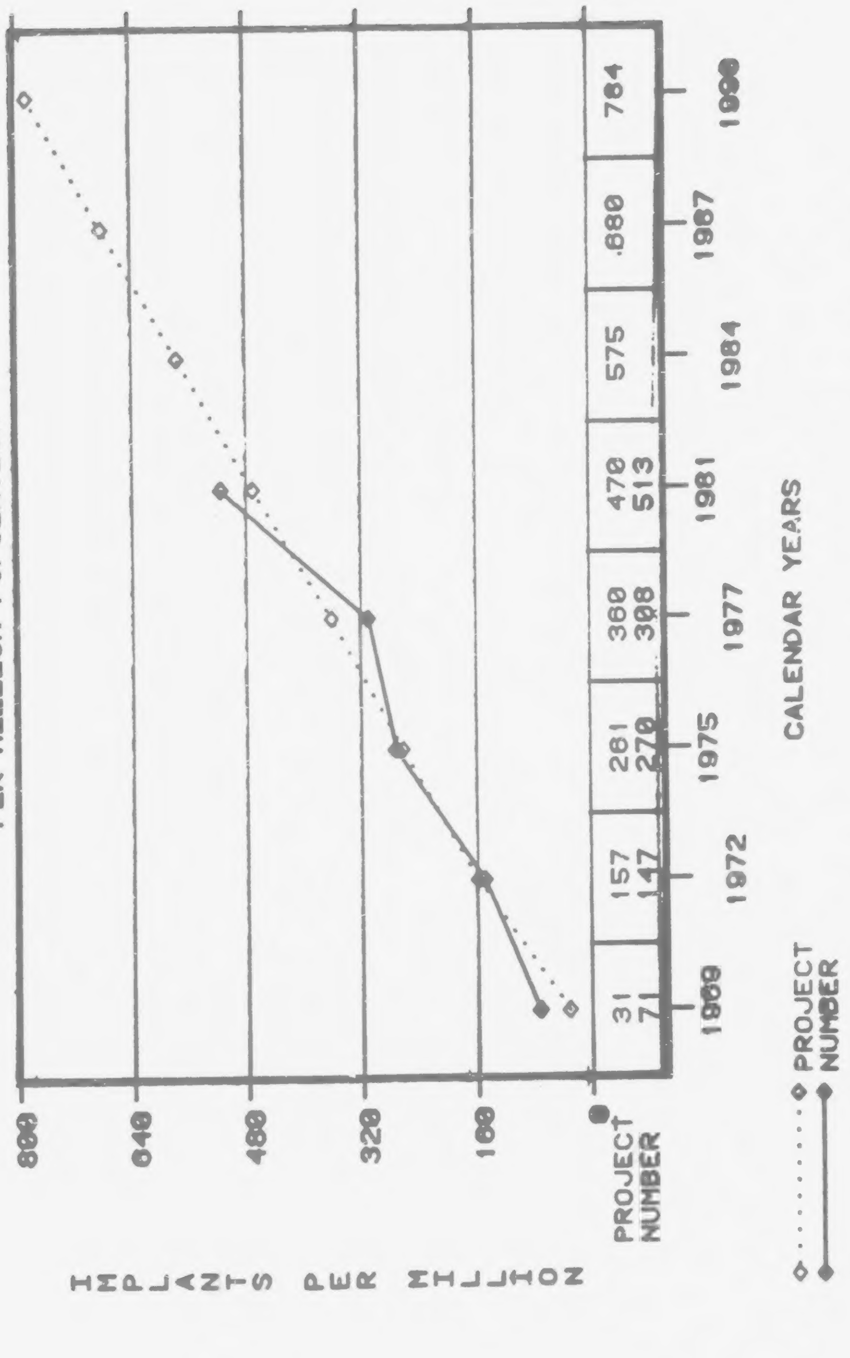
2400 estimated number of cases for which Medicare did not receive credit
(20,000 replacements X12%)

$24,000,000 estimated cost to Medicare for replacement operations in warranty situations
(2400 cases X $10,000)

$8,774,400 estimated value of the pulse generators
(2400 cases X $3,656)

CONCLUSIONS

PROJECTED RATE OF IMPLANTS PER MILLION POPULATION



135,930

Expected Implants in 1984

236.4 Millions Population

Est. Rate of Implants

X 575 per Million Pop.

= 135,930

108,744

Expected Medicare Implants in 1984

135,930	expected implants
.80%	Medicare
= 108,744	

21,749

Expected Medicare Replacements in 1984

$$\begin{array}{r} 108{,}744 \\ \times 20\% \\ \hline = 21{,}749 \end{array}$$

$217.5 MILLION

EXPECTED COST OF
MEDICARE REPLACEMENTS
(84)

(21,749 X $10K)

2,675

Expected Number of Recalls in 1984

$$\begin{array}{r} 21{,}749 \\ .123 \\ \hline = 2{,}675 \end{array}$$

$26.8 MILLION

EXPECTED VALUE OF RECALLS
(84)

(2,675 X $10K)

3,545

Expected Number of Warranty Situations in 1984

$$\begin{array}{r} 21{,}749 \\ \times\ .163 \\ \hline = 3{,}545 \end{array}$$

$35.5 MILLION

EXPECTED VALUE OF WARRANTIES
(84)

(3,545 X $10K)

6,220 Instances Involving Recalls or Warranties in 1984

$$\begin{array}{r} 21{,}749 \\ \times\ .286 \\ \hline =\ 6{,}220 \end{array}$$

$62.2 MILLION

EXPECTED VALUE OF RECALLS & WARRANTIES
(84)

(6,220 X $10K)

153,272

Expected Implants in 1986

238 MILLION POPULATION

Est. Rate of Implant per

X 644 Million Population

= 153,272

122,617

Expected Medicare Implants in 1986

153,272	Expected Implants
X .80	Medicare
= 122,617	

24,523

Expected Medicare Replacements

In 1986

$$\begin{array}{r} 122{,}617 \\ \times .20 \\ \hline = 24{,}523 \end{array}$$

$245.2 MILLION

Expected Cost of Medicare Replacements
in 1986

(24,523 X $10K)

3,016

Expected Number of Recalls In 1986

$$\begin{array}{r} 24{,}523 \\ \underline{\times\ .123} \\ =\ 3{,}016 \end{array}$$

$30.16 MILLION

Expected Value of Recalls in 1986

(3,016 X $10K)

3,997

Expected Number of Warranty Situations in 1986

$$\begin{array}{r} 24{,}523 \\ \underline{\text{X}.163} \\ = 3{,}997 \end{array}$$

$39.97 MILLION

Expected Value of Warranties in 1986

(3,997 X $10K)

7,013

Instances of Recalls & Warranties in 1986

$$\begin{array}{r} 24{,}253 \\ \underline{\mathrm{X}.286} \\ = \ 7{,}013 \end{array}$$

ISSUES

RECALLS:

MANUFACTURERS' Limiting their liability

WARRANTIES:

lack of off set provison under PPS

98TH CONGRESS
2d Session
HOUSE OF REPRESENTATIVES
REPORT
98-861

DEFICIT REDUCTION ACT OF 1984

THE COMMITTEE OF CONFERENCE

SUBMITTED THE FOLLOWING

CONFERENCE REPORT

[To accompany H.R. 4170]

JUNE 23, 1984.—Ordered to be printed

PACEMAKER REIMBURSEMENT REVIEW AND REFORM

Sec. 2304. (a)(1) The Secretary shall issue revisions to the current guidelines for the payment under part B of title XVIII of the Social Security Act for the transtelephonic monitoring of cardiac pacemakers. Such revised guidelines shall include provisions regarding the specifications for and frequency of transtelephonic monitoring procedures which will be found to be reasonable and necessary.

(2)(A) Except as provided in subparagraph (B), if the guidelines required by paragraph (1) have not been issued and put into effect by October 1, 1984, and until such guidelines have been issued and put into effect, payment may not be made under part B of title XVIII of the Social Security Act for transtelephonic monitoring procedures, with respect to a single-chamber cardiac pacemaker powered by lithium batteries, conducted more frequently than—

(i) weekly during the first month after implantation,

(ii) once every two months during the period representing 80 percent of the estimated life of the implanted device, and

(iii) monthly thereafter.

(B) Subparagraph (A) shall not apply in cases where the Secretary determines that special medical factors (including possible evidence of pacemaker or lead malfunction) justify more frequent transtelephonic monitoring procedures.

(b)(1) The Secretary shall review, and report to the Committees on Energy and Commerce and Ways and Means of the House of Representatives and the Committee on Finance of the Senate, regarding the appropriateness of the amounts recognized as reasonable under part B of title XVIII of the Social Security Act for physicians' services associated with implantation or replacement of pacemaker devices and pacemaker leads. Such review shall take into account the amounts recognized as reasonable with respect to such procedures and the time and difficulty of such procedures at the current time in comparison with such amounts and the time and difficulty of such procedures at the time the amounts for such procedures were first established under such part.

(2) The Prospective Payment Assessment Commission, established under section 1886(e) of the Social Security Act, shall review and report to the Committee on Ways and Means of the House of Representatives and the Committee on Finance of the Senate regarding the appropriateness of the payment amounts provided under section 1886(d) of such Act for inpatient hospital services associated with

implantation or replacement of pacemaker devices and pacemaker leads. Such review shall take into account the time, difficulty, and costs associated with such procedures at the current time in comparison with the time, difficulty, and costs associated with such procedures upon which the payment rates for such procedures under part A of title XVIII of such Act are based.

(3) The Secretary and the Commission shall each complete the review described in paragraph (1) or (2), respectively, of this subsection and report on such review not later than March 1, 1985.

(c) Section 1862 of the Social Security Act is amended by adding at the end the following new subsection:

"(h)(1)(A) The Secretary shall, through the Commissioner of the Food and Drug Administration, provide for a registry of all cardiac pacemaker devices and pacemaker leads for which payment was made under this title.

"(B) Such registry shall include the manufacturer, model, and serial number of each such device or lead, the name of the recipient of such device or lead, the date and location of the implantation or removal of the device or lead, the name of the physician implanting or removing such device or lead, the name of the hospital or other provider billing for such procedure, any express or implied warranties associated with such device or lead under contract or State law, and such other information as the Secretary deems to be appropriate.

"(C) Each physician and provider of services performing the implantation or replacement of pacemaker devices and leads for which payment is made or requested to be made under this title shall, in accordance with regulations of the Secretary, submit information respecting such implantation or replacement for the registry.

"(D) Such registry shall be for the purposes of assisting the Secretary in determining when payments may properly be made under this title, in tracing the performance of cardiac pacemaker devices and leads, in determining when inspection by the manufacturer of such a device or lead may be necessary under paragraph (3), and in carrying out studies with respect to the use of such devices and leads. In carrying out any such study, the Secretary may not reveal any specific information which identifies any pacemaker device or lead recipient by name (or which would otherwise identify a specific recipient).

"(E) Any person or organization may provide information to the registry with respect to cardiac pacemaker devices and leads other than those for which payment is made under this title.

"(2) The Secretary may, by regulation, require each provider of services—

> *"(A) to return, to the manufacturer of the device or lead for testing under paragraph (3), any cardiac pacemaker device or lead which is removed from a patient and payment for the implantation or replacement of which was made or requested by such provider under this title, and*
>
> *"(B) not to charge any beneficiary for replacement of such a device or lead if the device or lead has not been returned in accordance with subparagraph (A).*

"(3) The Secretary may, by regulation, require the manufacturer of a cardiac pacemaker device or lead (A) to test or analyze each pace-

maker device or lead for which payment is made or requested under this title and which is returned to the manufacturer by a provider of services under paragraph (2), and (B) to provide the results of such test or analysis to that provider, together with information and documentation with respect to any warranties covering such device or lead. In any case where the Secretary has reason to believe, based upon information in the pacemaker registry or otherwise available to him, that replacement of a cardiac pacemaker device or lead for which payment is or may be requested under this title is related to the malfunction of a device or lead, the Secretary may require that personnel of the Food and Drug Administration be present at the testing of such device by the manufacturer, to determine whether such device was functioning properly.

"(4) The Secretary may deny payment under this title, in whole or in part and for such period of time as the Secretary determines to be appropriate, with respect to the implantation or replacement of a pacemaker device or lead of a manufacturer performed by a physician and provider of services after the Secretary determines (in accordance with the procedures established under subsection (d)) that—

"(A) the physician or provider of services has failed to submit information to the registry as required under paragraph (1)(C),

"(B) the provider of services has failed to return devices and leads as required under paragraph (2)(A) or has improperly charged beneficiaries as prohibited under paragraph (2)(B), or

"(C) the manufacturer of the device or lead has failed to perform and to report on the testing of devices and leads returned to it as required under paragraph (3).".

(d) The Secretary of Health and Human Services shall promulgate final regulations to carry out this section and the amendment made by this section prior to January 1, 1985, and the amendment made by subsection (c) shall apply to pacemaker devices and leads implanted or removed on or after the effective date of such regulations.

15. Pacemaker Review and Reform (Section 2304)

Present law

The costs of inpatient hospital services with respect to the implantation of pacemakers, including the costs of the device, are subject to the new diagnosis-related group (DRG) prospective payment system. However, the costs of physicians' services for implantation and post-implantation monitoring of the devices are reimbursed under Part B. Post-implantation monitoring includes transtelephonic monitoring for which frequency guidelines have been established by the Secretary.

a. Guideline revision

House bill

The House bill would require the Secretary to revise the current guidelines on the frequency of transtelephonic monitoring.

Senate amendment

The Senate amendment includes a similar provision.

Conference agreement

The conference agreement follows the House bill.

b. Frequency guidelines

House bill

The House bill would provide that, if the Secretary fails to revise the guidelines by October 1, 1984, a specified frequency schedule would go into effect with respect to single-chamber cardiac pacemakers powered by lithium batteries. The House bill would provide that payment would not be made for monitoring which is more frequent than: (1) weekly during the first month after implantation, (2) once every two months during the period representing 80 percent of the estimated life of the device, and (3) monthly thereafter. Exceptions could be made based on special medical factors.

Senate amendment

The Senate amendment would require the issuance of revisions by April 1, 1984. No statutory schedule is set forth.

Conference agreement

The conference agreement follows the House bill with an amendment which provides that the frequency guidelines established by law will expire upon publication of the revised guidelines. The conferees expect that the revised guidelines will be published promptly. They further expect that the revised frequency guidelines will provide for exceptions where medically appropriate.

c. Payment review

House bill

The House bill would require the Secretary to review and report to the Congress on the appropriateness of the current Part B payment for physician's services associated with implantation or replacement of pacemakers and pacemaker leads. Such review would take into account the time and difficulty of the procedures compared to those when such rates were first established and take into consideration a reduction of such recognized rates by 20 percent. The House bill would require completion of the review by October 1, 1984.

Senate amendment

The Senate amendment includes a similar provision except that it would: (1) also require review of reimbursement for inpatient hospital services, and (2) not require the Secretary to take into consideration a reduction in recognized rates by 20 percent. The review and report would be due by April 1, 1984.

Conference agreement

The conference agreement follows the House bill with an amendment. The amendment requires a review of payments for implantation or replacement of pacemakers under both Parts A and B of Medicare, with the review of Part A payments conducted by the Prospective Payment Assessment Commission. Both studies must be submitted to Congress by March 1, 1985.

The conferees note that improvements in pacemaker implantation, reductions in the time required for such procedure, and changes in the difficulty and costs of such procedures have occurred over the past decade. Therefore, while the agreement eliminates the directive that the Secretary take into consideration a 20 percent reduction in recognized rates, the conferees expect the Secretary to consider whether some reduction in fees may be appropriate.

d. Registry

House bill

The House bill requires the Secretary, through the Food and Drug Administration, to provide a registry of all cardiac pacemaker devices and leads for which payment was made under Medicare.

The registry would include the manufacturer, model, serial number, and manufacturer's price, the name of the recipient, the date and geographic location of the implantation or removal, and the name of the physician, hospital or other provider. The registry would be required to include any express or implied warranties associated with the device and any other information which the Secretary deemed appropriate. The Secretary is prohibited from identifying any recipient of a pacemaker by name.

Senate amendment

The Senate amendment includes a similar provision. The registry information is substantially the same as that required by the House bill, except manufacturer price information is not specified. Submission of the information by the manufacturer would be a condition for any Medicare payments with respect to any devices or leads produced by that manufacturer.

Conference agreement

The conference agreement follows the House bill with an amendment. Inclusion of manufacturer price information in the registry is not required. Further, the amendment specifies that providers' and physicians' compliance with information requirements is a condition for Medicare payments with respect to implantation or removal of devices or leads.

The agreement further specifies that the purposes of the registry include tracing the performance of pacemaker devices and leads.

e. Return of device or lead

House bill

No provision.

Senate amendment

The Senate amendment would authorize the Secretary to require, as a condition of payment, that a provider furnish to the manufacturer information with respect to all patients bearing a device or lead for which Medicare payment was made or requested. The Secretary could also require that any device or lead removed from any such patient be returned to the manufacturer. Fiscal intermediaries could, pursuant to regulations, deny payment for replacements if the device or lead was not returned; beneficiaries could not be charged for replacements in such cases.

Conference agreement

The conference agreement follows the Senate amendment with a modification deleting the provision authorizing the Secretary to require that a provider furnish the manufacturer with information.

f. Testing

House bill

The House bill would provide that in any case where the Secretary had reason to believe that replacement of a pacemaker was related to its malfunction, the Secretary would be permitted to require the testing of such device by the FDA or that FDA personnel be present at testing by the manufacturer.

Senate amendment

The Senate amendment includes a similar provision. In addition, it would authorize the Secretary to require the manufacturer to test or analyze each returned cardiac pacemaker device or lead and provide the test results to the provider who returned it to the manufacturer, together with information as to any warranty coverage.

Conference agreement

The conference agreement follows the Senate amendment, except that it strikes the provision permitting the Secretary to require the FDA to do the testing.

g. Manufacturer reports

House bill

No provision.

Senate amendment

The Senate amendment would authorize the Secretary to require any manufacturer to provide to the FDA: (1) a written report with respect to any adverse reaction and any defect (within 10 days of the date on which the manufacturer is notified) and (2) an annual report summarizing clinical experiences with devices and leads including information on all removals, deaths, adverse reactions, device or lead defects, and the results of tests performed on all returned devices and leads.

Conference agreement

The conference agreement does not include the Senate amendment. The conferees understand that the Secretary is developing Mandatory Device Experience Reporting regulations, pursuant to section 519 of the Federal Food, Drug, and Cosmetic Act, which would establish requirements comparable to those set forth in the Senate amendment. The conferees did not wish to duplicate the provisions of those regulations or establish requirements inconsistent with them. The conferees expect the regulations to be issued soon and expect that they will accomplish the purposes of the Senate amendment.

h. Bonds

House bill

No provision.

Senate amendment

The Senate amendment would require manufacturers to post a bond or provide other assurances as the Secretary deems appropriate to ensure compliance.

Conference agreement

The conference agreement does not include the Senate amendment.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care
Financing Administration

Memorandum

Refer to: FQA-722

Date JUL 02 1984

From Director
Bureau of Eligibility, Reimbursement and Coverage

Subject Replacement of Medtronic Defective Leads/Pacemakers (Your memorandum of April 10, 1984)—ACTION

To Regional Administrator
Philadelphia

This will advise you of the actions you should take with regard to the issue of payment for claims involving replacement of the defective leads manufactured by Medtronic, Inc., which are currently under Food and Drug Administration recall.

On June 13 we met with officials of Medtronic to discuss the extent and nature of the leads problem. The discussion addressed relevant legal, policy and reimbursement issues.

We are working with the Office of General Counsel to resolve the various questions raised by the specific case of Lancaster General Hospital, and to formulate national policies on Medicare's responsibility for reimbursement for services related to the defective Medtronic lead, as well as to defective medical equipment in general.

The statute (Section 1862(b)(1)), the legislative history, and the regulations make clear that Medicare is the secondary payor where services are covered under a liability insurance policy or plan (including a self-insured plan). The law prohibits Medicare payment where payment has been made or can reasonably be expected under any "liability insurance." Section 405.322(b) of the regulations specifically includes product liability insurance within the definition of that term. Since we have been informed that Medtronic has product liability insurance, the liability insurance provision is applicable to this situation.

The regulations recognize that it is not appropriate to deny benefits solely because a beneficiary has the right to file a liability claim, since this does not in itself constitute a reasonable expectation of payment by the insurer. In this regard, Section 405.324 of the regulations provides that conditional Medicare benefits may be paid if a Medicare beneficiary has filed or has the right to file a liability claim against a party that allegedly caused an illness or injury and that if the beneficiary receives payment from a liability insurer, the individual must refund the conditional payment. (The instructions for making and recovering conditional payments are contained in section 3419.4G of the MIM.) Section 405.324 of the regulations also provides that HCFA has an independent right of action against a liability insurer or the responsible party if the insurer has not made payment.

Therefore, you should instruct contractors to make conditional payment for these claims, provided that the medical necessity criteria commonly applied to pacemaker replacement claims are met. (The replacement of defective leads is, of course, presumptively medically necessary.) Such conditional payments will be subject to Medicare's right to recover its payments either from any beneficiary who has received a payment from Medtronic's liability insurer or by direct government action against Medtronic and its insurer.

In making conditional payment we suggest that you adapt the beneficiary repayment agreement procedure for contested auto no fault cases described in §§3945.2 and 3945.3 of the Regional Office Manual. This procedure calls for consultation with the Regional Attorney (RA) in deciding whether or not, and in how many cases, to obtain a repayment agreement. Regional office staff should also point out to the RA the implications of requiring a beneficiary repayment agreement in all the disputed Medtronic cases, including the administrative burdens, and the fact that HCFA would be obligated to pay providers in any case and the fact that, even if the beneficiary refused to sign a repayment agreement we would require such repayment. (Medicare Intermediary Manual §3419.4E points out that repayment is required even if the beneficiary is not notified of his obligations to do so.) Also, your staff need not make the contacts with Medtronic or its insurer that would ordinarily be made under §3945.3, since this has already proved fruitless.

We will advise you further as matters are resolved. The Office of Eligibility Policy has the lead in developing national policy on this issue; if you have any further questions please call Herb Pollock, FTS 934-4978.

Henry R. Desmarais

Henry R. Desmarais, M.D.

JUL 11 1984

Don

Can you answer question on 2304? Thanks, JC

NOTE TO: Carol Walton
John Jansak
Ralph Howard

SUBJECT: Implementation of 84 Reconciliation--ACTION

We will get an updated regulations plan from ORM in the next few days showing the Deputy Administrator's decisions on the need for regulations, their priority and their actuarial savings estimates.

Coming out of that meeting, I have some issues I'd like you to consider:

- Section 2304 -- Are there payment communication links that must be established? -- OPOP
- Section 2319 -- From an audit and rate establishment standpoint, what is the practical effect of this section, given where we currently stand on rate setting and audit? -- OFO
- Section 2344 -- Given the assumption that our regulations had already given us this authority, how much practical help is this new legislation and, therefore, how hard should we push for a high priority on the reg? -- OPA

We will discuss these issues at a planning meeting when we receive the update from Rozann.

John C. Berry
John C. Berry

DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration

Public Health Service

Memorandum

Send, material [illegible] 2 [illegible]
to [illegible] [illegible] Aug. 1.

(1) Background - VA and FDA registries, [illegible]
- mfgrs. registries and [illegible]
2, Industry profile
3, [illegible] - just [illegible] and [illegible] - Ask Holton
4, [illegible] Medicare data.

Date · July 19, 1984

From Assistant Director for Intragovernmental Liaison, CDRH

Subject Implementation Strategy for Pacemaker Registry Legislation

[illegible]

To Cardiac Pacemaker Registry Task Force

I'm sure by now most of you have heard that Congress has passed and the President has signed a major tax/spending bill that has as one provision the establishment of a national registry for cardiac pacemakers and leads. Many of you are probably somewhat familiar with the general requirements of the bill and with FDA's role vis-a-vis HCFA.

With this new law now at our "doorstep," we must focus our attention on developing a nuts-and-bolts strategy for implementing it, one that takes into consideration how the registry will be funded, where in the Center it will be housed, how FDA will interface with HCFA, etc. This is what I see as the primary goal of this task force to which you've been appointed.

In undertaking this task, I should remind you that the pacemaker registry issue was identified as a high priority issue by Center senior staff at the "go away" last month. You may know that a follow-up session to the go-away has been scheduled for August 1, at which time senior Center staff management will grapple with major management problems. Although time is extremely short between now and this upcoming meeting, it would be desirable for us to arrive at the basics of an implementation strategy, and perhaps some recommendations and options.

In order to do this, I have set up a meeting on Tuesday, July 24 at 1:00 in T-400. At this point, I'm unable to project how long the meeting will run, but I'd ask that you make arrangements to devote most of the afternoon to this meeting.

I'd like to share some additional facts with you. First, we're aware that both HCFA and PHS staff have begun to "gear up" for this legislation. Thus we can assume that FDA will be contacted shortly about its plans for carrying out this activity, although I've been informed that it is unlikely PHS will ask for a formal implementation plan. Next, we're aware that Senator Heinz and his Aging Committee may hold hearings this fall to review the status of the Medtronic lead situation and our efforts to establish a pacer registry. Third, until decisions are made regarding which Center component(s) will take on lead responsibility for the registry and the other requirements of the bill, Bonnie Malkin and I, along with OMS, will coordinate this activity. As we move more toward negotiations with HCFA, the development of budget and staffing proposals, etc., OMS will assume primary responsibility.

Let me close by describing the material that's provided under the enclosed tabs.

- Tab A: A list of task force members and the component/organization each person represents.
- Tab B: Contains an agenda for Tuesday's meeting, in addition to a summary of the basic charge to the group.
- Tab C: A copy of the statutory language pertaining to the registry along with provision-by-provision summary of Congressional intent as agreed to by House and Senate conferees.
- Tab D: Contains a budget summary that was prepared by Donna Lenahan and other Center staff, and was presented to Department and Congressional staff during debate on the bill.
- Tab E: Two letters; the first is one both Dr. Koop and Mr. Villforth received from Dr. Joel Nobel of the National Implant Registry (and ECRI) that implicitly suggests that FDA utilize the services of the already operational NIR; the second one is from a physician affiliated with a private, multi-center registry that took over the pilot pacer registry FDA operated in the 1970's. (I include these only as a reminder that setting up the registry on an extramural basis is indeed an option worth considering.)

I hope the above information and the enclosed material will help prepare you for Tuesday's meeting. Should you have any questions between now and then, please contact either Bonnie or me at 443-6220.

Robert C. Eccleston

Attachments: Tabs A-E

Addressees:

Mr. Eccleston, OCD
Ms. Malkin, OCD
Ms. Lenahan, OMS
Mr. Rahmoeller, ODE
Mr. Hooten, OC
Dr. Scott, OTA
Mr. Weinstein, OSR
Ms. Johnson, OST
Dr. Skufca, OHA
Ms. Hardy, OLI
Mr. Landa, GC

cc: Mr. Benson
Mr. Goldstein
Ms. Suydam

Attachment A.

Cardiac Pacemaker Registry Task Force

1. Robert C. Eccleston, OCD
2. Bonnie H. Malkin, OCD Phil [illegible]
3. Donna M. Lenahan, OMS
4. Glenn A. Rahmoeller, ODE
5. William F. Hooten, OC
6. Walter L. Scott, OTA Bill [illegible]
7. Leslie S. Weinstein, OSR
8. Wendy S. Johnson, OST
9. Robert A. Skufca, OHA
10. Janet G. Hardy, OLI
11. Michael M. Landa, GC

Attachment B.

AGENDA FOR THE INITIAL MEETING OF THE CARDIAC PACEMAKER REGISTRY TASK FORCE

Tuesday, July 24 — 1:00 P.M. (T-400)

Introduction/Task Force Charge	R. Eccleston
History of Legislation and Overview of New Law	R. Eccleston
Summary of HCFA's Intent re Implementation of New Law	D. Lenahan
Outline of Implementation Plan: Format and Contents	P. Spiller
General Discussion of Implementation Issues	Task Force Members
Assignments/Scheduling of Next Meeting	R. Eccleston

Overall Charge

- To reach agreement on the interpretation of the law and FDA's obligations under it.
- To develop recommendations/options for the major issues regarding implementation, such as;
  - What Center componet(s) will have lead responsibility;
  - how this activity will be supported;
  - what role FDA will have vs. HCFA; and
  - what interagency relationships (formal and informal) need to be established with HCFA.

Attachment C.

[Please see June 23, 1984 Appendix item, above, for Pacemaker provisions of Deficit Reduction Act of 1984.]

Attachment D.

FDA RESOURCE IMPLICATIONS -- CARDIAC PACEMAKER REGISTRY REQUIREMENTS

The proposed cardiac pacemaker requirements (H.R. 4170), if passed as introduced, would have a number of cost implications for FDA. While H.R. 4170 includes both a House and Senate version, which would impose slightly different requirements, our initial cost estimates are the same for both versions -- 15 FTEs and $1.5 million. These estimates are based on the assumption that FDA will conduct the testing of pacemakers or leads.

Our estimates reflect annual costs. It should be noted that, while costs associated with promulgating regulations are one-time costs, roughly the same level of effort would be required, once these regulations are in place, for increased monitoring and compliance activity in subsequent years. We are assuming that 120,000 pacemaker/lead implants/replacements will be entered into the registry per year and that the devices currently implanted in patients prior to the effective date of the new law will not be registered.

DETAIL OF COST ESTIMATES

	FTE	CONTRACT	TOTAL $000
Regulatory development, implementation and compliance monitoring & follow-up (regulation development in the first year will be replaced by increased monitoring in subsequent years)	7		280
Automated Registry System	1	600	640
Report Review	2		80
Device Testing & Failure Analysis	8 1/		520
	15	600	1,520

1/ FTEs associated with device testing and failure analyses are calculated at $65,000; all others are $40,000.

DFM 6/84

Attachment E.

National Implant Registry

Plymouth Meeting PA 19462
• TWX 510-660-8023

DVISORY BOARD

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Chairman
Ophthalmology
University

AGENCY

June 22, 1984

Mr. John C. Villforth
Director
National Center for Devices and
Radiological Health
HFZ-1
5600 Fisher's Lane
Rockville, MD 20857

Dear Mr. Villforth:

We are writing you in response to the news that H.R. 4170 has passed both the House and the Senate, and has gone to Conference Committee. You are undoubtedly aware that H.R. 4170 includes a provision that requires the FDA to set up a reporting and tracking system whereby hospitals can register cardiac pacemakers and pacemaker leads. Setting up such a registry within the FDA would be costly and a waste of tax dollars, since a comprehensive system for keeping track of all implants and implant recalls - the National Implant Registry - is already operational nationwide.

The National Implant Registry, a nonprofit organization, registers all types of implants and notifies hospitals and physicians of product hazards and recalls. The Registry was established in 1982 after an investment of two years and more than $200,000 to develop the necessary computer systems and software. Its development was undertaken because the need for such a service was recognized by ECRI (formerly the Emergency Care Research Institute), the nation's foremost nonprofit health technology research, evaluation, and information organization. ECRI's mission is to evaluate the safety, reliability and cost-effectiveness of medical devices. In 1973 Senate testimony, ECRI specifically stated the need for an implant registry for pacemakers. After almost a decade of federal inaction, we undertook that responsibility, supported by foundation funds. A copy of this testimony is enclosed.

Requiring hospitals and physicians to register surgical implants is a vital part of quality patient care. However, for Congress to require that a system registering pacemakers be set up from scratch would be enormously wasteful. The National Implant Registry has been furnishing this service to health care providers at minimal cost and could provide the needed data to either the FDA or to pacemaker manufacturers without the substantial delay and expense required to establish a new system, quite possibly at either little or no cost to the government.

June 22, 1984
Mr. John C. Villforth
Director
National Center for Devices and
Page 2

An additional objective of this provision of H.R. 4170 is to collect statistical data on the failure rates of pacemakers and to put an end to abuse of federal funds when these devices are replaced. Determining pacemaker reliability does not require registering all pacemakers but only the registration of a significant sample of each type on the market. This could be easily achieved without the use of federal money merely by encouraging hospitals to utilize the National Implant Registry.

The requirements for registering patients laid out by H.R. 4170 represents the first involuntary registering of patients and clinical data with a federal agency and is therefore likely to invoke serious questions about confidentiality of patient medical records and data collection - a problem that the National Implant Registry has already solved. Futhermore, H.R. 4170 does not take into account that there will be much duplication of data and paperwork as many hospitals are already supplying this data to a number of different record-keeping networks including the National Implant Registry. At a time when most institutions are swamped with paperwork, this is an unrealistic demand.

Enclosed is background information for both the National Implant Registry and ECRI. We strongly suggest that this provision of H.R. 4170 be revised, in conference, to allow the Registry to fulfill the function specified, even on a nonexclusive basis.

We will be pleased to provide any further information that you may require and look forward to your views on this matter.

Sincerely,

Joel Nobel

Joel J. Nobel, M.D.
President

Susan Lalli-Ascosi

Susan Lalli-Ascosi, R.N.
Director for Hospital
Services

JJN/SLA/bjn
013815 013863
Enclosure

JUL 5 1984

Joel J. Nobel, M.D.
President
Ms. Susan Lalli-Ascosi
Director for Hospital Services
National Implant Registry
5200 Butler Pike
Plymouth Meeting, Pennsylvania 15462

Dear Dr. Nobel and Ms. Lalli-Ascosi:

This is in response to your letters of June 22 to me and Dr. Koop concerning the pending Congressional legislation that will, when enacted, require FDA to establish a national registry for cardiac pacemakers and leads. I appreciate your calling to my attention the services of the National Implant Registry.

I should note that since your letter, the bill has moved closer to final passage, with House and Senate conferees agreeing to a final proposal comprised of language from both versions. I understand that the full House and Senate approved the legislation on June 27, and that the main thrust of the bill has not changed from the earlier proposals.

Given that the main premise of this legislation is to curb unnecessary Medicare expenditures through a quality control system of recording the implantation and warranty dates and testing pacers and leads reported to have malfunctioned, we will need to consult with the Health Care Financing Administration (HCFA) about data and cost sharing. We are, at present, awaiting the final wording and passage of the bill before deciding on implementation procedures. If FDA decides to contract for certain data collection and analysis in support of the registry, we will probably issue a request for extramural proposals. At that time, we would welcome your proposal.

Sincerely yours,

/s/ John C. Villforth

John C. Villforth
Director
Center for Devices and
Radiological Health

PACEMAKER CENTER
UNIVERSITY OF SOUTHERN CALIFORNIA SCHOOL OF MEDICINE
PARKVIEW MEDICAL BUILDING • 1420 SAN PABLO ST • LOS ANGELES, CA 90033 • (213) 225-1555

July 11, 1984

Mr. John Villforth
Director of Center for
Devices and Radiological Health
5600 Fishers Lane
Rockville, Maryland 20857

Dear Mr. Villforth:

As you know my colleagues, Drs. Victor Parsonnet, Seymour Furman, Robert Hauser, Bernard Goldman, and I have been vitally interested in the performance levels of permanent cardiac pacemakers, including pulse generators and leads. We have had a ten year of commitment to the collection of data from our centers as a collaborative effort. We are, of course, watching with considerable interest the move by the Federal Government towards a central registration system, for a large aliquot of pulse generators and leads, which will be under the aegis of the Food and Drug Administration.

Because of our particular interests and background, we would appreciate the opportunity to establish a dialogue between ourselves and the Food and Drug Administration as to the future direction of any governmental or governmental sponsored national cardiac pacemaker registration system. We are particularly concerned about the maintenance of a high quality patient and physician-need oriented thrust to such a registry. Because of our unique experience in the collection of high quality concentrated data, we would be especially interested in exploring the possibility of the development of a detailed, unique, multicentric, concentrated data base for the assessment, on an ongoing basis, of not only hardware performance but the clinical basis and expectation of cardiac pacing in general.

I would be very pleased to discuss these questions with you at your convenience.

Looking forward to hearing from you in the near future, I remain,

Respectfully,

Michael Bilitch, M.D.
Associate Professor of Medicine

MB:kh

cc: Dr. Hauser
Dr. Furman
Dr. Parsonnet
Dr. Goldman
Dr. Harthorne
Dr. Waldo

7/27/84
Pacemaker Registry

GUIDELINES FOR PREPARING LEGISLATIVE IMPLEMENTATION PLANS

PURPOSE

The purpose of these guidelines is to establish PHS policy and procedures for the preparation and review of plans for implementing newly enacted legislation. Legislative Implementation Plans (LIPs) are to be prepared by the agency or staff office which has lead responsibility for the legislation.

The purpose of the LIP is to provide the Assistant Secretary for Health (ASH) and the Office of Health Planning and Evaluation (OHPE) with information on program implementation.

CRITERIA FOR DETERMING NEED FOR LIP

A. Criteria which will be used for determining the need for a LIP include the following:

if a new program is to be established that will require policy development, staffing and budget justification;

if the legislation will change existing program policy; and

if implementation will involve coordinating activities between another DHHS Operating Division (OPDIV) or Federal agency.

For other legislation, plans should be developed and managed internal to the particular organization.

B. The agency or staff office will be notified by memorandum from the Deputy Assistant Secretary for Health Planning and Evaluation when a LIP is due.

C. When a LIP is necessary for a law or section of a law and requires input from more than one agency or office, lead responsibility may be assigned to one agency or staff office for coordinating preparation of the LIP.

SUBMISSION OF PLANS

A. The level of detail in a LIP will vary with the complexity of the legislation. However, the LIP shall be detailed enough so that ASH and the reviewing agencies/offices will understand the steps which the lead organization, and any other affected organizations, plan to take for implementing the legislation.

B. The LIP shall use the following format and contain such information as is applicable:

1. The title and Public Law number.

2. The date enacted and effective date, if different.

•3. a. A brief summary of the purposes of the Act legislative background that has bearing on the specific provision requiring action by PHS.

   b. A section-by-section analysis, if appropriate, shall be appended to the LIP

4. If new legislation is affected by existing legislation (e.g., civil rights laws, the Privacy Act, the Freedom of Information Act, etc.), delineate the effects.

•5. Identify any PHS, DHHS OPDIV or other Federal agencies that will be involved in implementing the law or section of the law addressed by the LIP, and indicate the nature and scope of the involvement; e.g., "Funding in the amount of $_____ for the first year will be provided by Agency Y via a memorandum of Agreement."

•6. Describe the major actions required to implement this legislation and provide a timetable for each action; e.g., establishing a grant or loan program.

•7. State and discuss any significant policy or procedural issues raised by the legislation. If there will be prblems in implementing the legislation, discuss the anticipated problems in terms of a plan for resolving them.

•8. If a legal interpretation of the Act is needed, indicate the points that need interpretation. If legal opinion has been obtained, it should be incorporated in the discussion of Item 7 above.

•9. List all new or revised regulations that will be required. If required, identify other organizations that should participate in preparing them.

   a. Predict when specifications for regulations, or a draft of the regulations, will be completed by the program and forwarded to the Office of General Counsel.

b. Predict when the Notice of Proposed rulemaking and the final regulations will be sent to ASH.

General Counsel should participate in decisions concerning whether regulations to fulfill legal requirements or policy objectives are needed.

10. The agency or staff office Delegation Control Officer shall indicate if delegations of authority are needed. If they are, identify the authority or authorities and specify by and to whom the delegation(s) should be made.

11. When the legislation authorizes or reauthorizes programs of Federal financial assistance and/or direct Federal development (except R&D and training programs), the LIP is to contain an analysis concerning the program's applicability to the intergovernmental review requirements of Executive Order 12372, as implemented in 45 CFR Part 100.

12. If a report to the Congress is required, give the title and the due date. A Congressional Report Implementation Plan shall be submitted to the PHS Congressional Reports Coordinator no later than 30 days after the LIP has been submitted.

•13. State the total dollar authorization and appropriation level for each year and indicate the amount to be used for each section of the law. If PHS, OS or some other Federal agency is to provide funds, indicate the amount and source of funds. If a supplemental budget request is needed, state the amount and the date by which the request will be submitted.

•14. If additional staff is needed, indicate how many, and how the additional staff will affect the organizational structure.

•15. Indicate any proposed organizational changes required by the legislation or desired by the organization. State when functional statements will be submitted.

16. State if any advisory committees will be needed and, if so, the scope of responsibilities for the committee(s).

17. If the law requires participation of another PHS agency, office, or DHHS OPDIV, there should be evidence of approval of the LIP by the organization concerned.

C. Ten complete copies of the LIP are to be submitted to OHPE 30 days from the date of the notifying memorandum. For complex legislation, or for legislation which requires coordination with other agencies, offices, or OPDIVs, more time may be needed to prepare the LIP. In such cases, the preparing organization shall notify OHPE that more time is needed and give a new submission date.

REVIEW PROCESS

A. OPHE will coordinate the LIP review. Reviewing organizations will be selected on the basis of the subject matter of the particular Act.

B. The ASH will approve all LIPs. The preparing agency or staff office will be notified by memorandum of approval.

JUL 2 3 1984

NOTE TO: Henry R. Desmarais, M.D.

SUBJECT: Implementation of pacemaker provision (Section 2304) of The "Medicare and Medicaid Budget Reconciliation Amendments of 1984."--ACTION

We would like to get your agreement as to how to proceed with implementation of this provision, since it requires inter-agency coordination and agreement with FDA, and has some relatively short due dates. There are two separate provisions in Section 2304 on which decisions as to Medicare regulations are needed. One provision (item 3, below) ties Medicare coverage and reimbursement for both initial pacemaker and lead implants and replacements to physician and provider compliance with a pacemaker registry provision (which will be the responsibility of FDA), while another provision (item 4, below) ties Medicare coverage and reimbursement for pacemaker and lead implants and replacements to an inspection provision, which is couched in discretionary terms (i.e., ". . . the Secretary may, by regulation, require . . .").

With regard to item 3, the question is, who should have the lead in developing the regulation, FDA or HCFA? With regard to item 4, the question is, should implementation of this provision be deferred until some relevant uncertainties--the Medtronic lead problem, PRO review of pacemaker implantations, and the type and timeliness of information available from the FDA registry--are either resolved or at least more settled than they are likely to be in the near future?

Summary of Section 2304: There are four different parts to this provision:

(1) Implementation of revised transtelephonic pacemaker monitoring guidelines by October 1, 1984 (subsection (a));

(2) A report by The Secretary of HHS on the reasonableness of physician charges for implantation of pacemakers and a review and report by the Prospective Payment Assessment Commission on payments to hospitals for pacemaker implantation, both due by March 1, 1985 (subsection (b)); and

(3) The establishment by FDA of a pacemaker registry, the imposition of a reporting requirement on Medicare providers and suppliers, and discretionary authority to make Medicare payment for initial implants and replacement conditional upon compliance with the registry requirements, due by January 1, 1985 (subsection (c));

(4) A discretionary provision denying Medicare coverage and payment to providers for pacemakers or leads not submitted for inspection and testing to the manufacturer, if so required.

Assuming we publish our pacemaker monitoring instructions timely, the first provision will not require a regulation. The second provision requires only a report. Therefore, there is a need for regulations only with regard to the third and fourth provisions.

The third provision, although placed in title XVIII (section 1862 is amended by adding a new subsection (h)), is concerned primarily with the establishment of a pacemaker registry by FDA, ((h)(1)(A) and (B)) whose purpose ((h)(1)(A)) will be to:

(1) help determine when payments may be properly made under Medicare;

(2) trace the performance of pacemaker and leads;

(3) determine when inspection by the manufacturer is required; and

(4) carry out studies of pacemaker systems.

Although the establishment and maintenance of the registry is clearly delegated to the FDA, HCFA would presumably be responsible for rules the Secretary promulgates with respect to the provision's impact on providers and physicians under Medicare. One Medicare requirement with respect to the registry is mandatory--that physicians and providers supply information to the FDA for inclusion in the pacemaker registry with respect to both initial implants and replacements (section (h)(1)(C))--and another ((h)(4)(A)), although prefaced by a discretionary "may," enforces the mandatory provision by authorizing withholding of payment to physicians or providers who fail to submit information to the registry. In our opinion, while this second requirement is discretionary we think it should be put into regulations; although we already have broad regulatory authority to withhold payment to providers and suppliers which do not comply with reporting requirements, we think enforcement of the registry provision will be facilitated by a regulatory provision specifically withholding Medicare payment when the reporting requirement is not complied with. Both of these requirements are relatively minor in terms of regulatory language, since they may be affected by amending existing medicare regulations.

Lead responsibility--possible options: There are two options available in these split authority situations--(1) co-ordination by some designated authority at the HHS level of the separately developed of regulations of FDA and HCFA; or (2) assignment of the lead to one agency or the other, with the subordinate agency supplying their portion to the lead agency. We favor the second option with lead responsibility given to FDA. Our reasoning is as follows:

Using a lead agency, rather than HHS co-ordination:

a. Agencies are geared to producing regulations within specific schedules whereas HHS is geared primarily to clearance processes.

b. Where HHS has the lead, the issue will be coordinated by a person lacking the specialized knowledge of the agencies, and there is a greater chance that some necessary steps will not be identified and assigned.

Using FDA as a lead agency:

a. The registry regulation will likely be the more complex and difficult provision to prepare, since it will be a new provision, whereas the HCFA provisions may be done via amendments to existing regulations, which can easily be appended to the FDA regulations.

b. The FDA provision must be completed by January 1, 1985; whereas the HCFA provision, while effective January 1, 1985, is dependent to some degree on the registry being in place and operational in order to be effective. The registry provision is, therefore, a higher priority than the discretionary HCFA provisions.

The fourth provision which consists of section (h)(2), (h)(3), and (h)(4)(B) and (C), permits The Secretary to require providers to return to manufacturers for testing any pacemaker or lead implanted or replaced ((h)(2)(A)) and not to charge beneficiaries if the devices have not been returned ((h)(2)(B)); to require manufacturers to test the devices (presumably at the manufacturer's expense), and to report the results to the provider, together with any warranty information; to require that FDA personnel be present at the testing if it is suspected that the pacemaker or lead has malfunctioned ((h)(3)); and to deny payment if the provider (h))(4)(B)) or the manufacturer ((h)(4)(C)) fails to perform any of its responsibilities under this provision.

As noted at the beginning, this provision is couched in the discretionary "may". In addition, it obviously requires more extensive consultation and preparation than the third provision. Moreover, its implementation and degree of specificity will depend on the actual functioning (not just regulatory requirements) of FDA's pacemaker registry. The legislation seems, in fact, to imply that some experience with the actual operation of the registry is expected, since it refers to information the Secretary receives from the registry as a basis for requiring that FDA personnel be present at the testing of a pacemaker or lead.

In addition, our current pacemaker activities may well affect how this provision may be developed. These include the ultimate disposition of the Medtronic lead issue and the data and actions flowing from the PRO 100 percent review of pacemaker implants. It is possible that these activites will reduce or eliminate the need for any elaborate regulatory provision in this area. Consequently, we recommend that this provision be deferred until such time as we have a clearer view of what will need to be done and how the registry will affect our ability to do it.

We seek your concurrense on two points: (1) that we request the Secretary to assign the respective responsibilities of the third provision to FDA and HCFA with an FDA lead; and (2) defer development of regulations on the fourth provision.

Stan Katz

Stanley A. Katz

DEPARTMENT OF HEALTH AND HUMAN SERVICES

JUL 23 1984

TO : John C. Berry

SUBJECT : Section 2304 - Pacemaker Registry (Your Note of 7/11/84)—INFORMATION

Section 2304 requires the Secretary, through the FDA, to provide a registry of all pacemaker devices and leads for which payment is made under Medicare. The registry must include:

1. manufacturer
2. model
3. serial number
4. recipient
5. date
6. geographic location
7. physician name
8. hospital or other provider
9. warranty information (no precise guideline)
10. anything else the Secretary deems appropriate

All of the above items (except possibly 10) are available to the medical review entity. The intermediary would have access to only 4, 5, 6, 7, and 8 in the bill process. We have suggested informally at the staff level to HSQ that the PRO would be a more suitable data collection agent than the intermediary, and that the PHDDS from the PRO to HSQ or some other PRO to HSQ reporting mechanism would be a better reporting vehicle than PATBILL/UNIBILL. They are still considering this.

NOTE: PATBILL/UNIBILL now contains the ICD-9-CM procedure code to indicate pacemaker insert, which alerts the PRO to develop, and current instructions require medical review of all such cases.

Carol J. Walton

cc: John Jansak

BPO-0422:TSpruill:smf 7/16/84

File Copy

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
	Spruill	7/16			
		7/17			
	Walton	7/23			

7/24/84

TO: (Name, office symbol, room number, building, Agency/Post)	Initials	Date
1. Henry Desmarais		
2. Martin Kappert		
3. Judy Boggs		
4.		
5.		

☐ Action	☐ File	☐ Note and Return
☐ Approval	☐ For Clearance	☐ Per Conversation
☐ As Requested	☐ For Correction	☐ Prepare Reply
☐ Circulate	☐ For Your Information	☐ See Me
☐ Comment	☐ Investigate	☐ Signature
☐ Coordination	☐ Justify	☐

REMARKS

Proposed to be added to the FY 86 Legislative Package. Please review and comment.

Thanks!

JUL 25 1984

LOGGED IN

Spec. Asst. HB

AAD ✓

Refer to: BQC by noon, Monday 7/30

DO NOT use this form as a RECORD of approvals, ~~concurrences~~, disposals, File ~~clearances, and similar~~ actions

FROM: (Name, org. symbol, Agency/Post)

Sandy Lichty OAAP

Room No.—Bldg.
325-H

Phone No.
245-7063

5041-102

★ U.S. GPO: 1980—341-529/20

OPTIONAL FORM 41 (Rev. 7-76)
Prescribed by GSA
FPMR (41 CFR) 101-11.206

Authority to Recover Medicare Payments Associated with Recalled Medical Devices

Proposal:

Provide the Secretary with authority to recover costs associated with recalled or defective medical devices.

Goal:

To shift the financial burden for recalled or defective medical devices from Medicare to manufacturers of those devices.

Current Law and Problem:

Under current law, if a medical device is "recalled," and a Medicare beneficiary requires additional care to eliminate the risks associated with the recalled device, this care is considered "reasonable and necessary" and is paid for by Medicare. The Omnibus Reconciliation Act of 1980 added a provision to allow Medicare to be a secondary payer when payment has been made under a "liability insurance policy or plan (including a self-insured plan)." The implementing regulations for this provision state that Medicare can seek payment on behalf of a beneficiary (and this authority is being buttressed by Reconciliation proposals explicitly giving Medicare this subrogation authority). However, to exercise this authority, litigation must be brought, and Medicare may have the burden of proving that the device was defective, that the patient was injured, and that the manufacturer was responsible, or even negligent in States without a "strict liability" standard.

Although many medical devices have warranties, it is not clear that Medicare has the authority to enforce collection on devices. To the extent that providers voluntarily recouped funds under existing warranties, which were then reflected in cost reports, Medicare may have recovered some funds on defective devices. However, under the hospital prospective payment system, hospitals are not obliged to return any recovered funds to Medicare. Furthermore, warranties often are quite limited and do not cover many "recall" situations.

Manufacturers may issue a voluntary warning or recall that a medical device, either FDA-approved or investigational, may fail to perform or present an unreasonable risk to the public health. FDA may also require manufacturers to issue such a notice or seize devices. In these situations, physicians assess the potential risk to the Medicare beneficiaries and may decide to monitor patients' conditions more closely or to perform some more active treatment (such as replacing the possibly defective device) which would minimize the risk to beneficiaries. When such treatments are clearly linked to the manufacturer's warning (e.g., recommended by the manufacturer or the FDA in their notice), the Secretary should be allowed to recover payments for these services (and for a replacement device, if necessary).

Page 2

Justification:

Medicare expenditures are increasing rapidly. Because of the budgetary constraints, Medicare must become a prudent purchaser of services on behalf of its beneficiaries. If Medicare holds manufacturers of medical devices responsible for payments for health services resulting from the unreasonable health risks posed by their products, manufacturers will face incentives for minimizing these risks. This would result in significant savings to Medicare as well as improving the quality of care to beneficiaries.

The estimated Medicare payments for services associated with a 1984 voluntary recall of 18,000 to 27,000 defective cardiac pacemaker leads is approximately $96 million, and there have been other recalls of cardiac pacemaker this year. A preliminary BQC review indicates that in 1982, 12.4 percent of pacemaker replacements were due to a "recall" by the manufacturer and an additional 16.3 percent of replacements were for pacemakers that failed to perform up to the standards specified in the warranty.

This proposal would give the Secretary permissive authority to require medical device manufacturers to reimburse Medicare for payments for care resulting from a device which failed to perform or posed an unreasonable risk, as indicated by a warning or "recall." Conditional payments for the services and replacement device, if necessary, would be made to providers, and then, HCFA would recover its payments from the manufacturer.

Beneficiary Impact:

This proposal could improve the quality of medical devices available for use as well as slowing the growth in Medicare's expenditures.

Cost: (millions)

Personnel Requirements:

Positions
FTEs

See Ellen
FOI Room
114

Tom 7/31 file

Tom
Can you draft responses to some [illegible] items?
[illegible]
8/13.

Policy
Procedures
(Chow & comply)

INTERОFFICE MEMORANDUM

Memo: [45908.4129928.BHM]
Date: Fri 27-JUL-1984 11:28
From: Malkin, Bonnie
Dept: OCD-IOCD
Tel: 301-443-6220

8/22/84
Assignments due as soon as possible.

TO: Eccleston, Robert (RCE)
TO: ROBERT SKUFCA (HARD-COPY)
TO: Hooten, William F. (WFH)
TO: LES WEINSTEIN (HARD-COPY)
TO: Rahmoeller, Glenn (GAR) ✓
TO: JAN HARDY (HARD-COPY)
TO: KATHY SCHROEHER (HARD-COPY)
TO: WENDY JOHNSON (HARD-COPY)
TO: WALTER SCOTT (HARD-COPY)

Return-Receipt requested
Subject: Action Assignments from 7/24 Pacemaker Registry Task Force Meeting and Date of Next Meeting

TO: Pacemaker Registry Task Force Members

FROM: Program Analyst, DPE, OMS

The following action assignments resulted from our initial task force meeting on 7/24. Responsible offices are in parentheses.

Background

- Research systems that currently register pacemaker devices. (ODE, OMS). FDA; IA; (Stimarc)
- Summarize in writing the legislative history and rationale behind the bill, including FDA's position. (OCD)
- Gather statistical information on the number of pacemaker and lead implantations per year, what percentage are covered under Medicare, and related data. (ODE, OMS) 150,000/year 80% by Medicare
- Develop a profile of the pacemaker industry. (ODE) (?)
- Research current FDA involvement in pacemaker testing. (OTA).
- Act as liaison with FDA's Division of Financial Management in preparing a supplemental budget request to support implementation of the bill. (OMS)

Interpretation of the Bill

- o Provide a written determination on the following questions of interpretation of the bill:
  - -- whether all pacemakers and leads for which payment is requested under Medicare must be registered, or whether registering a sampling of devices may be sufficient (GC)
  - -- whether the term "devices" means just pacemakers and leads or whether it also includes monitoring and programming devices (ODE) } waiting for answer from [illegible] staff
  - -- whether the FDA can access and use manufacturers' registry data or require that "providers" provide the required data to manufacturers directly (GC)
  - -- what regulations need to be promulgated, whether FDA or HCFA should most appropriately take the lead in doing so, and within what time frames (OSR, GC)
  - -- under what circumstances can HCFA withhold payment, and can payment be withheld for the device and/or the procedure (OCD, OMS)
  - -- what does "may" mean within the bill versus "shall" (OLI)
  - -- what portions of the bill must be implemented by January 1, 1985 and what portions can be implemented after January 1 (OLI).
- o Explore the impact of the bill on reuse of pacemaker devices (OTA, OHA).

Implementation of the Registry

- o Explore enforcement tools available under this bill. (GC).
- o Explore whether FDA would want to set a standard for accepting registrations of implantations not covered by Medicare. (ODE). yes
- o Explore the feasibility of establishing the registry in-house versus an extramural contract. (OCD, OMS).
- o Explore the feasibility of supporting the registry with an MOU or IAG with HCFA. (OST).
- o Determine which Center components should most appropriately implement various portions of the bill. (OCD, OMS).
- o Determine whether and how the registry system should mesh with DEN and MDR. (OC)

- Explore the establishment of criteria (at the Secretary's level) under which pacemaker devices should be tested, and under what circumstances FDA would want to be involved. (OST).

- o Explore the releasability (under FOI) of information gathered under this bill, and the extent and methods of distribution of analyses and reports (OSR).
- o Explore the feasibility of a system whereby a contractor could fill information requests and charge users. (OSR).

The information gathered in the performance of these assignments should be submitted in written form to Bonnie Malkin, HFZ-3, T-527, by C.O.B. Friday, August 10.

OUR NEXT task force meeting will be on Friday, August 17, in T-400 at 1:00 p.m. to discuss our findings. Thank you.

Donna Lenahan

AUG - 6 1984

OPA
Current status
8 6/24

Note To: Mr. Harvey Brook

Subject: Legislative Proposal on Pacemakers (Your Request dated July 30, 1984)—
INFORMATION

We recommend that this proposal not go forward. There are several technical problems and we question the policy direction. From a technical perspective, the proposal does not state how the goal is to be specifically accomplished. There seems to be an implicit premise that use of "secondary payer concepts" would accomplish the shift of reimplantation costs to the manufacturer. This cannot be readily accomplished under that authority.

- Pacemaker manufacturers do not provide for payments for reimplantation under any "insurance program."

- The hospital or physician supplies the pacemaker, and payment is included in the overall fee for pacemaker implantation. Thus, there is no contractual relation between the recipient and the manufacturer. Such a relationship would be necessary to rely on the "secondary payer concept."

In addition, the proposal should state exactly what authority the Secretary would be given, and how it would be enforced. As written, the proposal only states that it would be nice for the Secretary to recover some of the reimplantation cost in some instances.

From a policy perspective, we believe other options are available to HCFA which would address both short and long term concerns. In the short term, existing regulations should be modified to allow offsets for warranty payments received, or not received because providers have not taken necessary actions to collect on warranties. In the long run, the DRG's need modification. A separate DRG for reimplantation - reflecting collections for defective pacemakers - should be established. This approach has been discussed several times with OAAP. However, they have expressed a preference for the approach indicated in the legislative proposals, which would require HSQB and BPO to develop methods and procedures to solve a problem that exists because of a technical deficiency in existing regulations.

I believe the approach we have advocated will solve the short term problem immediately, and establish a basis for a longer run solution consistent with PPS. This direction is particularly attractive since we can achieve our goal within existing regulations. This is preferable to preparing a legislative proposal for possible introduction in May 1985 if clearance from the Department and EOMB are obtained.

We shall be pleased to discuss further our concerns and views with OAAP staff.

84 AUG 28 A 8:29

John C. Berry

BZavoina:pgh:7/31/84
860 Disc: Phyllis II
OAS CNO 7428

ROUTING AND TRANSMITTAL SLIP Date 8/6/84

O: (Name, office symbol, room number, building, Agency/Post) | Initials | Date

GAR

Meet Wed. at Twinbrook

Action	File	Note and Return
Approval	For Clearance	Per Conversation
As Requested	For Correction	Prepare Reply
Circulate	For Your Information	See Me
Comment	Investigate	Signature
Coordination	Justify	

EMARKS

For your Wednesday meeting.

NOT use this form as a RECORD of approvals, concurrences, disposals, clearances, and similar actions

IOM: (Name, org. symbol, Agency/Post) | Room No.—Bldg. | Phone No.

B Malkin

41-102

GPO : 1983 O - 381-529 (308)

OPTIONAL FORM 41 (Rev. 7-76)
Prescribed by GSA
FPMR (41 CFR) 101-11.206

ation, OMS

the Pacemaker Registry

: to consider asking of

August 8 meeting on

as? Physician/surgeon?

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ns are involved?

o Does HCFA do anything with the data desides process claims? (Trend analysis?)

o Does HCFA keep/store the data? For how long? What kind of computer systems do they use?

o Who actually gets reimbursed?

Program Analyst, Division of Planning and Evaluation, OMS

Upcoming Meeting with HCFA Officials Regarding the Pacemaker Registry

See Below

The following is a list of questions we may want to consider asking of HCFA officials prior to or during our upcoming August 8 meeting on implementing the pacemaker registry.

The Medical Reimbursement Process

- Who makes claims to Medicare for pacers/leads? Physician/surgeon? Hospital? Patient?
- How are claims made? What information is currently required of claimants? (indications, initial or replacement implantation?)
- How are claims processed? What organizations are involved? what ~~kind~~ of Review/decision making processes?
- Does HCFA do anything with the data desides process claims? (Trend analysis?)
- Does HCFA keep/store the data? For how long? What kind of computer systems do they use?
- Who actually gets reimbursed?

- Does patient usually pay anything to ~~to~~ physician/hospital? If so, is it disclosed in the claim?

- Does HCFA currently get/use warranty information? Does the law allow for HCFA to take advantage of warranties?

- Under what circumstances are claims denied? Are they denied for failed ~~device failures~~ or recalled devices? Can payment be withheld for the device~~s~~, the procedure, or both?

Changes to HCFA Processes Resulting From the Registry

- What benefits do they see from having a registry? Do they think they will be able to reduce the number of reimbursements of questionable claims based on the kind of information they can get under a registry?

- What additional information would they want? In what form? How often? Any analyses?

- How will the claims review process/reimbursement criteria change with the registry and the legislation?

- What things would they look for to flag questionable claims?

Implementation Questions

- How do they see the excahnge of information occuring? Hard copy? Electronically? How often?
- What individuals from which organizations should most appropriately interact with the task force?
- Do they see any circumstances under which HCFA would want FDA to observe the testing of pacemaker devices?

If you can improve upon these questions (add to, consolidate, fine tune), please do.

Donna Lenahan

Addresses:

Glenn Rahmoeller
Bonnie Malkin
Bob Eccleston

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
Rockville MD 20857

August 13, 1984

MEMORANDUM OF MEETING

Between

David Holten
Chief Investigator
Senate Special Committee on Aging

David Schulke
Investigator
Senate Special Committee on Aging

and

Robert Eccleston
Assistant Director for Intragovernmental Liaison
Center for Devices and Radiological Health
FDA

Randy Veale
Director, Division of Anesthesiology and
Neurology Devices
Office of Device Evaluation
Center for Devices and Radiological Health
FDA

Jan Hardy
Legislative Analyst
Office of Legislation and Information
FDA

Wayne Mara
Legislative Analyst
Office of the Deputy Assistant Secretary
for Legislation/Health
HHS

This meeting was held at the request of the Committee staff to discuss their views on the implementation of the cardiac pacemaker registry provisions (section 2304) in P.L. 98-369, the "Deficit Reduction Act of 1984."

Under the new pacemaker registry law, FDA must provide for a national registry of pacemaker devices and leads to assist the Secretary in determining when payments may properly be made under Medicare. The Secretary could also use the registry to request FDA monitor manufacturer testing of potentially defective devices and leads. Furthermore, the Secretary is authorized to establish, by regulation, certain requirements for manufacturers, physicians, and other providers to meet in order to receive Medicare reimbursement. The new law requires that the registry and accompanying regulations must be in place by January 1, 1985.

The Committee's initial request was to obtain information on FDA's plans for implementing these provisions. However, Bob Eccleston told David Schulke that FDA's activity in this area was in the very early stages of development and that many issues still needed to be resolved, so we could not present them with any substantive plan at this time. With this understanding, the Committee staff chose to discuss their expectations of how these provisions should be implemented.

David Holten explained that Senator Heinz (chairman of the Aging Committee and sponsor of major pacemaker registry legislation in this Congress) maintains an active interest in this legislation and wishes to have a continuing dialogue with FDA to ensure that the pacemaker registry provisions will be implemented in the way they were envisioned by Congress. He stated Senator Heinz was very satisfied with the new law and that he got everything he wanted in his original bill S. 1622). This meeting would also serve to educate David Schulke since he will be replacing David Holten this week as chief investigator on cardiac pacemaker issues.

The Committee may hold oversight hearings on cardiac pacemakers as early as the fall, but Committee staff noted that the number of available "windows" was slim. They predicted a greater chance of hearings sometime soon after the new Congress convenes in January. It is not clear at this time what the focus of these hearings will be. David Holten indicated an interest in covering a broad range of pacemaker issues including reimbursement and warranties, and whether a registry would have spotted the Medtronics leads problem earlier. They are also interested in assessing the implementation of the pacemaker registry law. Jan Hardy checked with David Schulke on August 22 to get further clarification and status of these hearings. The Committee has not planned any hearings at this time and cannot give us guidance on the purpose and scope. However, David Schulke emphasized that a hearing could be called at the discretion of the Staff Director, and that he will let us know if that occurs.

The Committee staff discussed the provisions of the pacemaker registry law. They view the registry as having a two-fold purpose. The first, which they view as FDA's responsibility, is to protect the public health and to ensure the quality of health care by providing the necessary medical and techical expertise on pacemakers and leads. The second, is to determine when reimbursement is necessary, which they perceive as the responsibility of HCFA. They envision that both FDA and HCFA will use the registry in order to produce desired results in these two areas.

FDA staff and Committee staff discussed questions of joint implementation between FDA and HCFA, funding for the registry, and meeting the January 1985 deadline mandated in the new law.

Dave Holten suggested that an independent organization be established to implement the cardiac pacemaker provisions which would be composed of staff from FDA, HCFA, and manufacturers of pacemakers and leads. He also suggested that the trust funds that are maintained by fiscal intermediaries for pacemaker reimbursement could be given to FDA to maintain the registry. As another alternative to funding, he proposed that HCFA could help FDA pay for the registry.

The FDA staff explained the difficulties in meeting the six-month deadline for establishing the registry and developing the time consuming and complex regulations required by these provisions. Committee staff appeared to be sympathetic to these concerns, but wanted assurance that FDA will continue to move forward as fast as possible toward final implementation of these requirements. They expect that by the deadline, FDA will have a good sense of how the pacemaker registry will be implemented, whether additional legislation is necessary, and can identify any impairments, such as funding, that inhibit completing the implementation. FDA offered to provide a status report to the Committee around the time of the January deadline.

When the pacemaker registry bill was in conference, House and Senate conferees agreed to drop the requirement in the Senate version that manufacturers report to FDA on any adverse reactions to pacemaker devices and leads and submit annual reports to FDA summarizing clinical experiences with devices and leads. These requirements were deleted with the expectation that the Secretary of HHS will shortly issue mandatory device reporting (MDR) regulations which would accomplish the purposes of the Senate provisions. Dave Holten asked FDA staff for the status of the MDR regulations. FDA explained that the final rule was under review in the Department and must then go to OMB for clearance. He asked for a copy of the current draft, which we were unable to provide since the document is considered in-house. He also received assurance that the regulations will contain an "affirmative responsibility" to require manufacturers to report adverse reactions to FDA.

The new law also contains provisions (section 2309(a)) that require the Secretary to issue revisions to guidelines for payment under part B of the Social Security Act for the transtelephonic monitoring of cardiac pacemakers. Although the Committee views the implementation of these provisions as HCFA's responsibility, they asked for FDA input wherever possible.

The meeting ended with FDA's commitment to continue to keep Committee staff fully informed on the progress of its activities in implementing these provisions.

cc: Ann Rose
Wayne Mara
Bob Eccleston
Randy Veale
Pacemaker Registry Task Force
Henry R. Desmarais, M.D., HCFA
Stanley H. Katz, HCFA

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

AUG 14 1984

Henry R. Desmarais, M.D.
Director, Bureau of Eligibility,
Reimbursement, and Coverage
ATTENTION: Mr. Stanley H. Katz
Division of Medical Services
Coverage Policy, HCFA
Room 489, East High Rise Building
6325 Security Boulevard
Baltimore, MD 21235

Dear Mr. Katz:

Let me first express my thanks for allowing us to reschedule Wednesday's meeting with you and Dr. Desmarais. As we agreed during our telephone conversation, I have pulled together the enclosed list of questions and issues relating to HCFA reimbursement policies and procedures, which the Center's pacemaker registry task force has identified. In order for the task force to proceed with its deliberations in the development of implementation and funding options, we will need to discuss how you envision utilizing the data submitted to the registry.

It's critical, I think, that we work closely together on this activity to ensure that what we do in terms of establishing the registry is tailored to HCFA's operational needs. To reach this end, we feel it is important to have a fundamental grasp of what mechanisms HCFA currently uses in processing reimbursement claims for pacemaker and lead implantations and replacements. I hope the enclosed questions help to give you some idea of the type of information we feel we need to begin to implement the registry portion of the law.

During our talk, you indicated some interest in interacting with our task force. I wonder whether it would be more productive to invite you and other members of the BERC staff to attend the group's next meeting, which would give the task force as a whole an opportunity to ask questions and learn about HCFA's programs, as well to discuss different approaches to implementing the registry.

I will give you a call early next week to discuss the enclosed material and the rescheduling of our meeting. Should you have any questions in the meantime, please feel free to give me a call at FTS-443-6220.

Sincerely yours,

/s/ Robert C. Eccleston
Robert C. Eccleston
Assistant Director for
Intragovernmental Liaison
Center for Devices and
Radiological Health

Enclosure

cc: Cardiac Pacemaker Registry Task Force

FDA Questions For HCFA

1. Describe the HCFA reimbursement process, including who makes claims, how claims are made, and the information required in claims.

2. Describe how claims are processed, the type of information systems used by HCFA, how payment vs. non payment decisions are made, etc. Under what circumstances are claims denied (e.g. failed or recalled devices?)

3. How will the legislation affect the current reimbursement process, e.g. will HCFA require additional information on claims, how will claims be received, how will criteria for making payment decisions change, etc.

4. Does HCFA currently get/use warranty information? Does the law allow for HCFA to take advantage of warranties?

5. How does HCFA propose that the registry data be collected, analyzed, disseminated, and stored.

6. Does HCFA see any circumstances under which it would want FDA to observe the testing of pacemaker devices?

7. What benefits/problems does HCFA forsee in the new registry?

12a

regional letter
Medicare

MEDICARE PROCEDURAL
POLICY BRANCH

AUG 16 10 37 AM '84

Department of Health
and Human Services

Health Care Financing
Administration

Transmittal No. 84-5

DEP. DIV. MEDICARE
ELIGIBILITY POLICY

Date AUGUST 1984

FQA-62

Subject: Potential for Recovery of Medicare Payments from Liability Insurers for Medical Expenses Incurred in Connection with Defective Devices and Other Liability Situations—Action

Questions have been raised recently about Medicare's recourse when it makes payment for medical expenses associated with the replacement of defective devices, or with other corrective procedures required by such devices, particularly when significant numbers of beneficiaries are involved. An example of this type of situation is the repair or replacement of a medical device, such as a heart pacemaker, that requires hospital and medical services for which Medicare is billed, in addition to the cost of the device itself, for which Medicare may or may not be billed. The cost of such services, whether or not the device is covered by a warranty, may constitute damages that can be recovered from the manufacturer's liability insurer. A recent case of this kind has been an FDA recall order in connection with a specific type of pacemaker lead manufactured by Medtronic, Inc.

The statute (Section 1862(b)(1)) and the legislative history make clear that Medicare is the secondary payer where services are reimbursable under a liability insurance policy or plan (including a self-insured plan). The law prohibits Medicare payment where payment has been made or can reasonably be expected under any "liability insurance." The regulation pertaining to liability insurance (Sec. 405.324) recognizes that it is not appropriate to deny Medicare benefits merely because a beneficiary or a group of beneficiaries has filed or has the right to file a liability claim against a responsible party. Instead, the regulation permits Medicare to pay conditional benefits for treatment of an injury or illness that was allegedly caused by another party, and requires that the Government recover such benefits if payment is later made under liability insurance. The regulation further stipulates that the Government has an independent right of action against the liability insurer or responsible party, if the liability insurer has not made payment.

Where situations involving possible recovery of Medicare benefits paid in connection with defective devices are identified, claims by providers, physicians and beneficiaries should be paid conditionally. This is in accordance with the instructions in MIM §3419.4G and MCM §3340.8. In addition, consult with the Regional Attorney concerning possible referral of cases involving such claims to the Department of Justice for consideration of whether an independent Government claim should be pursued.

Currently, there are no instructions for dealing with this type of situation. We plan to issue instructions as soon as possible to contractors, providers of services, and Regional Offices (ROs) which will include policies and procedures for making and recovering conditional payments, including necessary contractor coordination with the RO to decide when a repayment agreement should be obtained. Those instructions will also deal with implementation of Sec. 2344 of the Deficit Reduction Act of 1984 (Pub. L. 98-369), which gives the Government specific subrogation rights where payment can be made under liability insurance. In the meantime, ROs should be alert to any situation involving potential recovery of Medicare payments from liability insurers for medical expenses incurred in connection with defective devices. Regular contacts with the Food and Drug Administration are planned to identify such situations, but those contacts will not obviate the need for an active RO and contractor role to identify situations in which the Government may wish to file independent liability claims. Contractor systems that identify claims involving the repair or replacement of medical devices may be useful in that regard.

Situations involving a large number of beneficiaries who may file individual or class liability insurance claims should also be investigated. Examples of this type of situation include product recalls other than by FDA, chemical or radioactive contamination of a community or other large group of people, disasters involving possible negligence by a party, etc. Such situations should be viewed as leads to be investigated for possible recovery of Medicare payments already made or for conditioning Medicare payments not yet made on repayment by the beneficiary, should a liability insurer subsequently make payment.

UNITED STATES CODE ANNOTATED

Title 21
Food and Drugs
§§ 1 to 800

Cumulative Annual Pocket Part

For Use In 1984

Replacing prior pocket part in back of volume

[illegible]
[illegible]
LIBRARY

Includes the Laws of the
98th CONGRESS, FIRST SESSION (1983)

For close of Notes of Decisions
See page III

CURRENT LAWS AND LEGISLATIVE HISTORY
Consult
United States Code
Congressional and Administrative News

ST. PAUL, MINN.
WEST PUBLISHING CO.

(5) the promulgation of a regulation under section 360f of this title (other than a proposed regulation made effective under subsection (b) of such section upon the regulation's publication) making a device a banned device,

(6) the issuance of an order under section 360j(f)(2) of this title, or

(7) an order under section 360j(g)(4) of this title disapproving an application for an exemption of a device for investigational use or an order under section 360j(g)(5) of this title withdrawing such an exemption for a device,

any person adversely affected by such regulation or order may file a petition with the United States Court of Appeals for the District of Columbia or for the circuit wherein such person resides or has his principal place of business for judicial review of such regulation or order. A copy of the petition shall be transmitted by the clerk of the court to the Secretary or other officer designated by him for that purpose. The Secretary shall file in the court the record of the proceedings on which the Secretary based his regulation or order as provided in section 2112 of title 28. For purposes of this section, the term "record" means all notices and other matter published in the Federal Register with respect to the regulation or order reviewed, all information submitted to the Secretary with respect to such regulation or order, proceedings of any panel or advisory committee with respect to such regulation or order, any hearing held with respect to such regulation or order, and any other information identified by the Secretary, in the administrative proceeding held with respect to such regulation or order, as being relevant to such regulation or order.

(b) Additional data, views, and arguments

If the petitioner applies to the court for leave to adduce additional data, views, or arguments respecting the regulation or order being reviewed and shows to the satisfaction of the court that such additional data, views, or arguments are material and that there were reasonable grounds for the petitioner's failure to adduce such data, views, or arguments in the proceedings before the Secretary, the court may order the Secretary to provide additional opportunity for the oral presentation of data, views, or arguments and for written submissions. The Secretary may modify his findings, or make new findings by reason of the additional data, views, or arguments so taken and shall file with the court such modified or new findings, and his recommendation, if any, for the modification or setting aside of the regulation or order being reviewed, with the return of such additional data, views, or arguments.

(c) Standard for review

Upon the filing of the petition under subsection (a) of this section for judicial review of a regulation or order, the court shall have jurisdiction to review the regulation or order in accordance with chapter 7 of title 5 and to grant appropriate relief, including interim relief, as provided in such chapter. A regulation described in paragraph (2) or (5) of subsection (a) of this section and an order issued after the review provided by section 360e(g) of this title shall not be affirmed if it is found to be unsupported by substantial evidence on the record taken as a whole.

(d) Finality of judgments

The judgment of the court affirming or setting aside, in whole or in part, any regulation or order shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification, as provided in section 1254 of title 28.

(e) Remedies

The remedies provided for in this section shall be in addition to and not in lieu of any other remedies provided by law.

(f) Statement of reasons

To facilitate judicial review under this section or under any other provision of law of a regulation or order issued under section 360c, 360d, 360e, 360f, 360h, 360i, 360j, or 360k of this title each such regulation or order shall contain a statement of the reasons for its issuance and the basis, in the record of the proceedings held in connection with its issuance, for its issuance.

(June 25, 1938, ch. 675, § 517, as added May 28, 1976, Pub. L. 94-295, § 2, 90 Stat. 560.)

§ 360h. Notification and other remedies

(a) Notification

If the Secretary determines that—

(1) a device intended for human use which is introduced or delivered for introduction into interstate commerce for commercial distribution presents an unreasonable risk of substantial harm to the public health, and

(2) notification under this subsection is necessary to eliminate the unreasonable risk of such harm and no more practicable means is available under the provisions of this chapter (other than this section) to eliminate such risk,

the Secretary may issue such order as may be necessary to assure that adequate notification is provided in an appropriate form, by the persons and means best suited under the circumstances involved, to all health professionals who prescribe or use the device and to any other person (including manufacturers, importers, distributors, retailers, and device users) who should properly receive such notification in order to eliminate such risk. An order under this subsection shall require that the individuals subject to the risk with respect to which the order is to be issued be included in the persons to be notified of the risk unless the Secretary determines that notice to such individuals would present a greater danger to the health of such individuals than no such notification. If the Secretary makes such a determination with respect to such individuals, the order shall require that the health professionals who prescribe or use the device provide for the notification of the individuals whom the health professionals treated with the device of the risk presented by the device and of any action which may be taken by or on behalf of such individuals to eliminate or reduce such risk. Before issuing an order under this subsection, the Secretary shall consult with the persons who are to give notice under the order.

(b) Repair, replacement, or refund

(1)(A) If, after affording opportunity for an informal hearing, the Secretary determines that—

(i) a device intended for human use which is introduced or delivered for introduction into interstate commerce for commercial distribution presents an unreasonable risk of substantial harm to the public health,

(ii) there are reasonable grounds to believe that the device was not properly designed and manufactured with reference to the state of the art as it existed at the time of its design and manufacture,

(iii) there are reasonable grounds to believe that the unreasonable risk was not caused by failure of a person other than a manufacturer, importer, distributor, or retailer of the device to exercise due care in the installation, maintenance, repair, or use of the device, and

(iv) the notification authorized by subsection (a) of this section would not by itself be sufficient to eliminate the unreasonable risk and action described in paragraph (2) of this subsection is necessary to eliminate such risk,

the Secretary may order the manufacturer, importer, or any distributor of such device, or any combination of such persons, to submit to him within a reasonable time a plan for taking one or more of the actions described in paragraph (2). An order issued under the preceding sentence which is directed to more than one person shall specify which person may decide which action shall be taken under such plan and the person specified shall be the person who the Secretary determines bears the principal, ultimate financial responsibility for action taken under the plan unless the Secretary cannot determine who bears such responsibility or the Secretary determines that the protection of the public health requires that such decision be made by a person (including a device user or health professional) other than the person he determines bears such responsibility.

(B) The Secretary shall approve a plan submitted pursuant to an order issued under subparagraph (A) unless he determines (after affording opportunity for an informal hearing) that the action or actions to be taken under the plan or the manner in which such action or actions are to be taken under the plan will not assure that the unreasonable risk with respect to which such order was issued will be eliminated. If the Secretary disapproves a plan, he shall order a revised plan to be submitted to him within a reasonable time. If the Secretary determines (after affording opportunity for an informal hearing) that the revised plan is unsatisfactory or if no revised plan or no initial plan has been submitted to the Secretary within the prescribed time, the Secretary shall (i) prescribe a plan to be carried out by the person or persons to whom the order issued under subparagraph (A) was directed, or (ii) after affording an opportunity for an informal hearing, by order prescribe a plan to be carried out by a person who is a manufacturer, importer, distributor, or retailer of the device with respect to which the order was issued but to whom the order under subparagraph (A) was not directed.

(2) The actions which may be taken under a plan submitted under an order issued under paragraph (1) are as follows:

(A) To repair the device so that it does not present the unreasonable risk of substantial harm with respect to which the order under paragraph (1) was issued.

(B) To replace the device with a like or equivalent device which is in conformity with all applicable requirements of this chapter.

(C) To refund the purchase price of the device (less a reasonable allowance for use if such device has been in the possession of the device user for one year or more—

(i) at the time of notification ordered under subsection (a) of this section, or

(ii) at the time the device user receives actual notice of the unreasonable risk with respect to which the order was issued under paragraph (1),

whichever first occurs).

(3) No charge shall be made to any person (other than a manufacturer, importer, distributor or retailer) for availing himself of any remedy, described in paragraph (2) and provided under an order issued under paragraph (1), and the person subject to the order shall reimburse each person (other than a manufacturer, importer, distributor, or retailer) who is entitled to such a remedy for any reasonable and foreseeable expenses actually incurred by such person in availing himself of such remedy.

(c) Reimbursement

An order issued under subsection (b) of this section with respect to a device may require any person who is a manufacturer, importer, distributor, or retailer of the device to reimburse any other person who is a manufacturer, importer, distributor, or retailer of such device for such other person's expenses actually incurred in connection with carrying out the order if the Secretary determines such reimbursement is required for the protection of the public health. Any such requirement shall not affect any rights or obligations under any contract to which the person receiving reimbursement or the person making such reimbursement is a party.

(d) Effect on other liability

Compliance with an order issued under this section shall not relieve any person from liability under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy provided him under such order shall be taken into account.

(June 25, 1938, ch. 675, § 518, as added May 28, 1976, Pub. L. 94-295, § 2, 90 Stat. 562.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 331, 352, 360c, 360g, 360j of this title.

CARDIAC DATACORP, INC.
1280 BLUE HILLS AVE.
BLOOMFIELD, CT. 06002 (203) 243-2986

May 18, 1984

Ms. Emelie A. Sconing
Supervisor, Beneficiary Services
Pennsylvania Blue Shield Medicare
P.O. Box 65
Camp Hill, PA 17011

RECEIVED
MAY 30 1984
[illegible] Program
[illegible]

Dear Ms. Sconing:

Enclosed is a copy of the most recent FDA Enforcement Report which places several pulse generators in a Class 1 recall.

CDI is currently monitoring approximately 2,000 of these pacemakers. It appears that some physicians may request more frequent monitoring for those patients implanted with the recalled pacemakers.

As in the past, CDI will furnish all documentation with our claims to support any of the physician's requests for more frequent monitoring which result in claims that exceed the Medicare payment parameters.

Please retain this recall notice for informational purposes in the event we request reviews on claims denied for "too many services".

If you have any questions, please feel free to contact me.

Sincerely,

Audrey Moir

Audrey Moir
Director,
Administrative Services

AM/cak

Enclosure

FDA Enforcement Report

Press Office
Food and Drug Administration
5600 Fishers Lane
Rockville, Md. 20857
301/443-4177

The FDA Enforcement Report is published weekly and contains information on prosecutions, seizures, injunctions, and recalls. The following is an explanation of these actions.

PROSECUTION: **A criminal action filed by FDA against a company or individual charging violation of the law. Prosecutions listed below have been filed with a court but not yet tried or concluded.**

SEIZURE: **An action taken to remove a product from commerce because it is in violation of the law. FDA initiates a seizure by filing a complaint with the U.S. District Court where the goods are located. A U.S. marshal is then directed by the court to take possession of the goods until the matter is resolved. The date listed is the date a seizure request is filed, not the date of seizure.**

INJUNCTION: **A civil action filed by FDA against an individual or company seeking, in most cases, to stop a company from continuing to manufacture or distribute products that are in violation of the law. Injunctions listed have been filed with the court but not concluded.**

RECALL: **Voluntary removal by a firm of a defective product from the market. Some recalls begin when the firm finds a problem, others are conducted at FDA's request. Recalls may involve the physical removal of products from the market or correction of the problem where the product is located.**

84-22

May 30, 1984

Recalls and Field Corrections:

Class I - *A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious, adverse health consequences or death.*

Product:	Kling Special Ham Cure, labeled to consist of 22 pounds 13-1/4 ounces of seasoning plus 7-1/2 ounces of cure (sodium nitrite), Recall #F-297-4
Code:	Seasoning #MM24116 Lot #C-12961, Cure #CU5963 Lot #C-12973
Manufacturer:	The Baltimore Spice Company, Baltimore, Maryland
Recalled by:	Manufacturer, by telephone April 16, 1984. Firm initiated recall.
Distribution:	Delaware
Size & Quantity:	Firm estimates none remains on market
Reason:	Excessive sodium nitrite.

Class II - *A situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. (Class II recalls are listed when received by the Press Office. Media reporters should contact the companies involved to obtain the most current information on the progress of recalls.)*

Product: Martha White brand Plain Enriched White Cornmeal in 2 pound bags, Recall #F-295-4
Code: 435331
Manufacturer: Martha White Mills, Inc., Huntington, West Virginia
Recalled by: Martha White Foods, Inc., Division of Beatrice Foods, Nashville, Tennessee, by telephone February 15, 1984. Firm initiated recall complete
Distribution: North Carolina, Virginia, West Virginia
Size & Quantity: 4,116 bags were distributed; firm estimates none remains on market
Reason: The North Carolina Department of Agriculture and the Virginia Department of Agriculture and Consumer Services reported aflatoxin contamination in excess of 20 ppb.

Product: OEC/Diasonics brand Mobile C-Arm X-ray Systems, Models 902 and DXR-5, Recall #Z-150/151-4
Code: All serial numbers for Models 902 and DXR-5
Manufacturer: OEC/Diasonics, Salt Lake City, Utah
Recalled by: Manufacturer. FDA approved the firm's corrective action plan April 26, 1984. Firm initiated field correction.
Distribution: Nationwide, Puerto Rico, Republic of China, Equador, Turkey, Korea, New Zealand, United Kingdom
Size & Quantity: 95 units of Model 902 and 22 units of Model DXR-5 were distributed
Reason: Noncompliance with performance standards for diagnostic X-ray systems and their major components in that the system fails to limit the X-ray beam to the visible area of the image receptor upon automatic return from the spot-film mode to the fluoroscopic mode.

Product: Sleep Sentry, a diabetic hypoglycemic reaction alarm device, Recall #Z-152-4
Code: All lots shipped prior to February 15, 1984
Manufacturer: Teledyne Avionics, Charlottesville, Virginia
Recalled by: Manufacturer, by letter February 15, 1984. Firm initiated field correction complete
Distribution: Nationwide
Size & Quantity: 493 units were distributed
Reason: The electronic board can separate from the metal case causing a short circuit to develop.

ROUTING AND TRANSMITTAL SLIP Date 8/20 [1984]

TO: (Name, office symbol, room number, building, Agency/Post)	Initials	Date
1. Glenn		
2.		
3.		
4.		
5.		

☐	Action	☐	File	☐	Note and Return
☐	Approval	☐	For Clearance	☐	Per Conversation
☐	As Requested	☐	For Correction	☐	Prepare Reply
☐	Circulate	☐	[✓ For Your Information]	☐	See Me
☐	Comment	☐	Investigate	☐	Signature
☐	Coordination	☐	Justify	☐	

REMARKS

attached: 1) agenda f. sept. pacemaker registry task force meeting, & 2) Draft decision meme on implementation strategy.

DO NOT use this form as a RECORD of approvals, concurrences, disposals, clearances, and similar actions

FROM: (Name, org. symbol, Agency/Post)
Dorsa Fenton

Room No.—Bldg.
T-515

Phone No.
443-5207

5041-102

OPTIONAL FORM 41 (Rev. 7-76)
Prescribed by GSA
FPMR (41 CFR) 101-11.206

☆ GPO : 1983 O - 381-529 (311)

Pacemaker Registry Task Force

Meeting Two: August 22, 1984
1:30 - 4:30, T-416

Agenda

1. Introductory Statement (Eccleston)
2. Report of meeting with Senate Committee on Aging (Hardy/Eccleston)
3. Recap last meeting (Eccleston)
4. Results of Selected Assignments

   - registry support options (Lenahan)
   - update on budget action
   - in-house vs. contract implementation

   - regulation promulgation (Weinstein)
   - what must be done by January 1, 1985, and what can be done later
   - FOI implications

   - meaning of term "pacemaker devices" (Rahmoeller)
   - do we want to set a standard for acceptance of non-Medicare implantations?

   - meaning of "may" vs. "shall" in the legislation (Hardy)

   - impact of the registry on device reuse (Lenahan)

   - should the registry system mesh with DEN and MDR, and how? (Hooten)

5. Options Paper Format/Timeframes (Eccleston)
6. New Assignments (Eccleston)
7. Next Meeting (Eccleston)

[Please see October 16, 1984 and December 4, 1984 Appendix items, below, for drafts of FDA discussion memo, "Implementation Strategy for Pacemaker Registry".]

5/22/84
[illegible] Weinstein

CARDIAC PACEMAKER REGISTRY

1. What regulations need to be written?

   The only regulation the bill says "shall" (must) be written is one that would require physicians and providers to submit information regarding implantation or replacement (amended 1862(h)(1)(C)).

   The bill says we also "may" (optional) by regulation require a provider to return a pacemaker to the manufacturer for testing (amended 1862(h)(2)) and require the manufacturer to test and may require FDA to be present (amended 1862(h)(3)).

   The bill also states (amended 1862(h)(1)(A) and (B)) that FDA "shall provide" for a registry which shall include certain information but it does not say that it has to be done by regulation. Amended 1862(h)(4) states that the Secretary may deny Medicare payment to physicians and providers (in accordance with procedures established to carry out the provisions of the bill) in the event of non-compliance, but does not say anything about a regulation.

   Section 2304(d) states that the Secretary "shall" (must) promulgate final regulations to carry out the provisions of the bill by January 1, 1985.

2. Which of the "may" provisions should we implement?

   This is a policy decision the Center must make based on a variety of factors (need, resources, budgetary restrictions, etc.).

3. Do we have to implement the "may" provisions at the same time as the "shall"?

   We don't have to, but if we don't it will look as if we have decided not to implement the optional provisions.

4. What does the January 1, 1985 deadline for promulgation of the final regulation apply to?

   Obviously, to the mandatory regulations regarding submission of information by physicians and providers (amended 1862(h)(1)(D)). It probably also applies to amended 1862(h)(1)(A) & (B) regarding providing for a registry to include specific information. Although this section does not mention "regulations," we should probably include it in the regulation requiring submission of data in order to set forth how the registry will be established, what data will be in it, when, how, by whom, and what form the data should be submitted, FOI implications, and other "housekeeping" or procedural provisions. The regulation should attempt to limit the data coming to us to preclude our being swamped by sources not required by the bill to submit.

5. What agency will write and publish the regulations?

This will have to be decided after discussions with HCFA. The options are: FDA alone, HCFA alone, FDA and HCFA jointly (though I am not sure if this can be done), or FDA do one regulation and HCFA do a companion regulation, each with a different focus (this was done by FDA and CDC regarding alpha-fetoprotein test kits).

6. Can FDA write the regulations even though the bill amends the Social Security Act?

Yes, because the bill says so. In the regulation, we will cite the Social Security Act as our authority rather than the Federal Food, Drug, and Cosmetic Act.

7. Will whatever regulations we decide to write have to be included in the FY 85 Regulation Plan?

Yes. In fact, it is already tentatively on the plan.

8. What are the Freedom of Information implications regarding releasability of information and distribution of analyses?

Information in a computer is a "record" and as such is subject to release (under FOI), but not automatically releasable because of the personal privacy and confidentiality exemption.

Analyses done by a contractor are releasable, but if we use a contractor and the information is received, stored, and manipulated by the contractor, it is possible that we could say there is nothing to be released because we do not have the record; the contractor is in possession of it. ([illegible])

If we receive, etc., the information in-house, probably only summaries of the data would be all that could be released. The reason for this is the data such as patient name, and physician name and provider name, would not be releasable. Also, manufacturer and type of pacemaker would not be releasable because they would reveal production and sales data which are confidential commercial information.

If the files are set up by FDA by patient name or number, there could be Privacy Act problems, but if individual patients ask for information about themselves, it is probably releasable. Individual physicians will be able to get information about themselves, also.

If we decide to write a regulation to implement 1862(h)(3) requiring manufacturers to test returned pacemakers and provide results to the providers, we may be asking for some FOI problems. Once the manufacturer gives the test results to a provider, then any member of the public could then get the test results from us (if we had them) even though the data would otherwise have been confidential (St. Jude case).

In any event, for any information we release under FOI, we charge $.10 a page and $10.00 an hour for hard copies. If it is all computer generated, we can charge actual cost (programming, staff time, etc.).

The regulations implementing the registry should have a section about FOI.

If we get the data from HCFA, we would need to know if that agency has regulations that affect the releasability of the data even though FDA has the registry.

Les Weinstein
Operations Staff
Office of Standards and
Regulations
Center for Devices and
Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Joanna

Health Care Financing
Administration

Region IV
101 Marietta Tower
Atlanta GA 30323

August 29, 1984

Mr. Allan Lazar, Director
Office of Medical Review
Health Care Financing Administration
1849 Gwynn Oak Avenue
Baltimore, Maryland 21207

Dear Mr. Lazar:

Re: 516-PRO Review Activity Report Form

One of our PROs called concerning the "Draft" instructions for completing the monthly 516 PRO Review Activity Report item IV.B Procedure Review-Pacemaker Reimplants (see Attachment A). Attachment B (page 60 of the "Draft") instructs PROs "...do not include the replacement of electrodes or generator packs only; a reimplant is defined as the total replacement of the old unit with a new one." (Emphasis added). We believe all situations: pulse generator and/or lead replacements should be reported by the PRO as a reimplant. We cannot comprehend why Central Office would define and restrict a reimplant to the total unit--both the pulse generator and the lead, because this deviates from what happens in the real world and virtually eliminates most reimplant reporting.

Earlier pacemakers consisted of three separate pieces of hardware: the pulse generator (commonly referred to as the pacemaker), the battery and the lead. More recently with the discovery of the more powerful lithium battery, the pulse generator and lithium battery are hermetically sealed to form a single unit. This not only reduces infection, but also eliminates the patient's annual trek to the operating table for a 'battery' change because the life expectancy of the pulse generator now ranges from two to seven years.

The lead is the second part of the pacemaker currently being used. The lead contains the electrode. Most leads contain a redundancy feature: there is always one or two good conductors left in one strand of the lead if one part should break or weaken. Moreover, adapters are available that enables one manufacturer's leads to be compatible with a pulse generator from another manufacturer. This eliminates unnecessary lead replacement when a different pulse generator is reimplanted. In fewer cases, the lead is the problem. Usually this is not discovered until surgery. In most of these cases, the pulse generator as well as the lead is replaced. Under your draft instructions these few cases are all that will be reported by the PRO. We believe the definition of reimplant should be "replacement of pulse generator and/or lead."

We have an observation about another section of this same report. Page 6 of Form 516, the PRO gathers warranty information about newly implanted or reimplanted pulse generators. Not all manufacturers offer warranties, as they are not required. The warranties that do exist include so many limitations that they are rendered worthless. Moreover, during a reimplant situation, the old warranty (if there was one) is the one that would apply. Rarely is this warranty available or benefits applied for. How then, does this data collection benefit the Medicare program? We realize that this data collection effort is part of the contract signed by all

PROs but if the process has outlived the need for the data, HCFA should eliminate the requirement.

In a Program Validation Study of fifty pacemaker reimplant patients conducted by us less than one year ago, we demonstrated that at least ten percent of the payments for pacemaker reimplants is due to factory recalls (Medicare's expense of the pulse generators, leads and attendant services totalled $52,579.66 by the hospital and $3,615 in surgeon's charges in our sample cases alone). The Food and Drug Administration is a good source for this recall information. A factory recall is a place where HCFA could pursue financial retribution by these companies where Medicare patients are concerned. This is an area where HCFA could demonstrate real dollars recovered. Perhaps the PRO collected data could be useful in this endeavor.

Please let us know what is decided about the "Draft" instructions concerning the definition of reimplants.

Sincerely yours,

Regina E. Williamson, for
C. D. Kimsey
Action Associate Regional Administrator
Divison of Health Standards and Quality

MEMORANDUM of MEETING

August 29, 1984

Between

Stanley Katz - Director, Mary Louise McIntyre - Acting Director, Ron Milhorn, and Sharon Hippler, of the Division of Medical Services Coverage and Policy, Bureau of Eligibility, Reimbursement, and Coverage Policy, HCFA

Jerry Selinger, M.D., and Charles Lawhorn - Health Standards and Quality Bureau, HCFA

Mary Ann Durham - Analyst, and Frank Spruill, Bureau of Program Operations, HCFA

Israel Braunner - Analyst, Office of Eligibility Policy, Bureau of Eligibility, Reimbursement, and Coverage Policy, HCFA

and

Robert Eccleston - Assistant Director for Intragovernmental Liaison, Glenn Rahmoeller - Director, Division of Cardiovascular Devices, Office of Device Evaluation, and Donna Lenahan - Program Analyst, Division of Planning and Evaluation, Office of Management and Systems, of the Center for Devices and Radiological Health, FDA

Janet Hardy - Legislative Analyst, Office of Legislation and Information, FDA

Subject: Implementation of the Pacemaker Registry

This meeting was requested by CDRH's Pacemaker Registry Task Force to discuss collaboration between HCFA and FDA in implementing the pacemaker registy. Other than telephone conversations, this is the task force's first contact with HCFA. In preparation for the meeting, Mr. Eccleston sent BERC Director, Dr. Henry Desmarais a package explaining our purpose in requesting the meeting and the topics we wanted to discuss (attached).

In discussing HCFA's claims review and reimbursement processes, we learned that through their Professional Review Organizations (PROs), much of the data required by the registry is already being collected by HCFA. PROs review Medicare/Medicaid claims for medical need, appropriateness, etc.

HCFA staff believe that the primary beneficiary of the registry data and the agency responsible for implementing it is FDA, not HCFA. However, they agreed that regulations written to implement the bill should be a joint effort between the two agencies.

The meeting resulted in two assignments to be completed by September 7: 1) both parties will develop specific data needs under the registry; and 2) BERC staff will research utilizing the PRO system for collecting registry data.

AUG 30 1984

Note To: John C. Berry

Subject: Current Status of Legislative Proposal on Pacemakers (Your Note of August 26, 1984)—INFORMATION

This is in response to your request for the status of the attached FY 86 legislative proposal. The Office of Legislation and Policy received comments on the proposal from the Bureau of Program Operations and Bureau of Quality Control. The comments are being evaluated by OLP staff. A recommendation will be made to Patrice Feinstein as to whether to include the proposal in the HCFA package.

We will inform you when a decision is reached.

TO:

John W. Jansak

Attachment

STATUS?

8 11/13

SEP 4 1984

TO : Stan Katz

SUBJECT : Pacemaker Registry—INFORMATION

Based on the meeting in your office on August 29 we have the following observations and suggestions:

A. Data Elements to be Collected

The data elements specified by section 2304 for inclusion in the registry are:

1. Manufacturer - We would propose that pacemaker manufacturers be identified by a three digit number to be assigned by the FDA, or by HCFA based upon identification of approved manufacturers by the FDA.

2. Model Number - Self explanatory. Perhaps FDA could tell us the length (number of digits in the longest to help in systems planning).

3. Serial Number - See number 2.

4. Recipient - We would propose that the recipient be identified by HIC number and surname.

5. Date - Self explanatory.

6. Geographic Location - If this means recipient we recommend zip code. If it means hospital location we propose provider numbers be used.

7. Physician Name - We propose the operating physician ID number reported for PRO purposes be reported. If name is needed it can be obtained where needed from the hospital or the PRO. Name would not be helpful without ID number and is not needed with ID number until it is necessary to contact the hospital or physician. The name would be easily obtainable at that time.

8. Hospital or Other Provider - We propose using the Medicare provider number.

9. Warrenty Information - No precise guidelines were furnished and FDA has no interest. We probably could use number of months, dollar limit, and any restrictions (i.e., parts, parts and labor, etc.) to the extent restrictions can be coded. — period =

10. Anything else the Secretary deems appropriate - It does not appear anthing else will be deemed appropriate from the provider. The ICD-9-CM procedure code now reported should be included to distinguish between pacemakers and leads.

B. Method of Collection

BPO and HSQB are still discussing the method of collection. No matter how the data is collected we need to define a reporting format to FDA in accordance with A above and a format for FDA to tell us of the items in C below.

C. What We Could Use from FDA

1. Notification of any recall of product by manufacturer, model, and serial number of applicable.
2. Periodic screening of records to identify cases where implants are performed for beneficiaries that have previously received implants, and notification to HCFA of such cases.
3. The benefit of any analysis they do.

The above information could be used to determine whether to pursue reimbursement for the cost of the pacemaker from the manufacturer of the original pacemaker.

Frank Spruill

Frank Spruill

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

SEP 9 198

Mr. Stanley Katz
Director, Division of Medical Services
Coverage Policy, BERC
Health Care Financing Administration
Room 489, East High Rise Building
6325 Security Boulevard
Baltimore, Maryland 21235

Dear Stan:

Many thanks for the time you and your colleagues spent with us on August 29. We found the discussion enlightening and productive, and I believe we made some headway in identifying potential areas of interagency collaboration. As agreed to at the close of the meeting, both of us were to develop a list of our own data requirements under the new pacemaker registry law. Enclosed you will find the material we have put together which is primarily directed to observing both short- and long-term safety problems associated with pacers and leads.

We look forward to receiving your information and to further talks about how we can work together to implement this law effectively while at the same time minimizing the burdens imposed by the Act on both of our agencies.

Sincerely yours,

Robert C. Eccleston
Assistant Director for
Intragovernmental Liaison
Center for Devices and
Radiological Health

Enclosure

FDA's responsibilities undc. the Deficit Reduction Act of 1984 regarding use of pacemaker registry data are stated in Sec. 2304(c), "...in tracing the performance of cardiac pacemaker devices and leads, in determining when inspection by the manufacturer may be necessary under paragraph 3, and in carrying out studies with respect to the use of such devices and leads." With this mandate in mind, the Pacemaker Registry Task Force compiled this list of data elements we believe would be necessary to perform the tasks.

- Data Elements Specified in the Bill as Being Required
  - manufacturer, model number, and serial number of device or lead
  - name of recipient of device or lead
  - date and location of implantation of device or lead
  - name of hospital or provider billing for procedure
  - any express or implied warranties associated with the device or lead.
- Additional Data Elements Necessary to Support Problem and Use Trend Analysis
  - whether the procedure is an initial implant or a replacement
  - for explants, whether the provider believes the explant is possibly, probably, or probably not, device related.
- Data Summaries, Reports
  - The task force believes the registry system should have the capability of searching the data by certain keywords and not others, e.g., keywords that might reveal confidential information.
  - Key words/phrases we would definitely want to search by include:
    - manufacturer
    - model number
    - serial number
    - date of procedure
    - possibly device related explant
    - probably device related explant
    - probably not device related explant
  - Actuarial analyses, i.e., failure/survival rates for a given manufacturer, model number or serial number for different time intervals (1-6, 7-12, 13-18, & 19-24 months) and overall.

The pacing profession in the U.S. has for years been interested in the establishment of a registry of this type for research purposes, traceability, and device performance monitoring. With the establishment of this system it is certain the profession will express a need for certain data that could be derived from the registry. At this time the task force cannot anticipate what all of these needs might be, but believes that there would be value in reasonably trying to meet them. Therefore, the system utilized to collect & analyze the registry data should be amenable to modifications as the need arises.

SEP 11 1984

Note to Stanley Katz

Subject: Warranty Information in Cardiac Pacemaker Registry — Your Oral Request at Meeting with FDA on 8/29/84

At the conclusion of the 8/29/84 meeting with FDA on implementation of section 2304 of the Deficit Reduction Act, you asked that participants provide, in their areas of program responsibility, specifications for data to be included in the cardiac pacemaker registry being developed by FDA.

In the area of warranties, since the statute requires that the registry include "any express or implied warranties ... under contract or State law," anything short of the complete text of any express warranties would be incomplete. That, plus the terms of any implied warranties under contract ~~or State law~~, should be required of the manufacturer. As to implied warranties under State law, we agree with your suggestion to Iz Brauner for a compendium of implied warranties by State. Since, according to Bob Jaye of OGC, in some States implied warranties are judicially rather than statutorily determined, such a compendium might have to be limited to statutory States. Bob said Regional Attorneys could help compile a compendium. He also said manufacturers would know about implied warranties by State because they have to know the potential exposure in marketing products, so manufacturers should be able to supply information for the compendium. We assume that from a program operations standpoint the controlling statute would be the law of the State where the procedure is performed rather than the State of manufacture.

Recognizing that the foregoing data would be difficult, if not impossible, to incorporate into an automated registry, we suggest that, if an automated registry is the option selected, the registry include only indicators of whether or not the device is covered by a warranty; if so, what parts are covered (e.g., pulse generator, leads, or entire pacemaker); whether or not repair or replacement services are covered; and where express warranty information may be readily obtained. Those data could be easily automated. The compendium of implied warranty information would be needed with or without the automated registry.

As you know, Iz Brauner is our contact on this matter. His phone number is 7-5139 (FTS 987-5139).

H Fishman
Harold Fishman

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

Health Standards and Quality Bureau
1849 Gwynn Oak Avenue
Baltimore, Maryland 21207

SEP 14 1984

NOTE TO: Robert Wren, Acting Director
Office of Coverage Policy

SUBJECT: Pacemaker Warranty Information for FDA's National Registry

This follows up a recent meeting between several Health Care Financing Administration (HCFA) components and the Food and Drug Administration (FDA) concerning the collection and use of cardiac pacemaker warranty information by HCFA and the FDA's task of establishing a National Registry for pacemaker devices, as required by the Deficit Reduction Act of 1984. Several members of my staff were present at that meeting. At the conclusion of the meeting Stan Katz asked each HCFA component to supply information about data on pacemaker devices and warranties which it now collects.

I have attached a copy of the pacemaker warranty information report which the Health Standards and Quality Bureau central office will soon be collecting from Utilization and Quality Control Peer Review Organizations (PROs). This report is to be submitted to HCFA on a monthly basis. In addition, PROs will, on a monthly basis, provide HCFA with the number of permanent cardiac pacemaker implants and reimplants reviewed and the number that are denied on the basis of medical necessity and appropriateness of the procedure.

We believe, however that the warranty information which PROs are now required to collect could be better and more efficiently collected through the new National Registry.

I trust this responds to Stan's request. If there are further questions, please call Kay Terry, at extension 47910.

Allan Lazar
Director
Office of Medical Review

Attachment

PACEMAKER REIMPLANT WARRANTY INFORMATION

PRIOR INSERTION DATA			REIMPLANT DATA		
DATE OF INSERTION	PACEMAKER NAME/SERIAL NO.	WARRANTY PERIOD	DATE OF INSERTION	PACEMAKER NAME/SERIAL NO.	WARRANTY PERIOD

TO : Philip Nathanson SEP 20 1984

SUBJECT : Processes for Obtaining Data to Implement Pacemaker Registry Required by Section 2304 of PL 98-369—ACTION

P.L. 98-369 requires the Secretary through the FDA to provide a registry of all pacemaker devices and leads for which payment is made under Medicare. The registry must include:

1. Manufacturer
2. Model
3. Serial number
4. Receipt
5. Date
6. Geographic location
7. Physician name
8. Hospital or other provider
9. Warranty information
10. Anything else the Secretary deems appropriate

Dr. [illegible] - Be sure & see a copy of Phil's reply.

10/2 - 10/12 Phil's Ofc - Not answered as yet.

11/14 See attached

All of the above items (except possibly 10) could be made relatively easily available for the medical review entity. The intermediary would not have access to 1, 2, 3, or 9. It is to HCFA's advantage to assist FDA in completing the registry because:

1. It can be done less expensively as a byproduct of either the billing or medical review processes, and
2. HCFA has an interest in the accuracy and usefulness of beneficiary and provider specific data and HCFA participation will result in HCFA identification numbers being used and validated during processing.

It appears to me that the least expensive way to maintain the registry would be to add a few steps to the medical review process when pacemakers are involved. Essentially the PRO would extract 1, 2, and 3 above in connection with medical review and report such data elements in the PHDDS. An alternative would be PRO reporting to the intermediary for intermediary reporting in UNIBILL but this would involve changing two records instead of one.

Another alternative is providing for a direct hospital to FDA reporting mechanism but this would be more costly for the hospital and probably less accurate; and as indicated above HCFA has an interest in accuracy.

May I have your views on incorporating the processes for reporting to the pacemaker registry in the medical review and PHDDS processes?

John C. Berry

BPO-0422:FSpruill:smf 9/4/84

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

6325 Security Boulevard
Baltimore, MD 21207

SEP 26 1984

Mr. Robert C. Eccleston
Assistant Director of Intergovernmental Liaison
Center for Devices and Radiological Health
Food and Drug Administration
Rockville, Maryland 20853

Dear ~~Mr. Eccleston~~: Bob

As agreed at the close of our meeting on August 29, we are enclosing material compiled by the various components in HCFA responsible for developing a list of data requirements under the new pacemaker registry law. (Section 2304 of the Budget Reconciliation Act of 1984.) These materials will have to be analyzed within HCFA to assure they are complementary and compatible with one another, but we believe you can make use of them in this rough form for initial planning purposes. Meanwhile, we will proceed with the task of developing a single list of data requirements for your use.

I believe that we should now set up a continuing FDA/HCFA workgroup to delineate and carry out the work that will need to be done by our respective agencies to implement the new law. In that regard we have already asked Mr. Frank Spruill of HCFA's Bureau of Program Operations to act as operations contact for purposes of coordinating and responding to your questions on such matters. He may be reached at 594-9156 (FTS-934-9156). We, of course, will continue to have overall responsibility for HCFA's portion of this project; however, we believe designation of an operations contact will enable you to obtain the necessary technical information and expertise you require regarding Medicare's claims operations in a more expeditious manner.

We are continuing to proceed on the assumption that FDA will have the overall lead for development of the registry regulations, while my division will furnish regulatory language and policy rationale for those provisions (1862(h)(1)(C) and (h)(4)(A)) dealing with the Medicare program requirements for physicians and providers with respect to compliance with the registry requirements.

Sincerely yours,

Stanley Katz

Stanley Katz
Director, Division of Medical Services
Coverage Policy
Bureau of Eligibility, Reimbursemnt
and Coverage

[Please see above appendix items for following memoranda, which were attached to September 26, 1984 letter to Eccleston, of FDA, from Katz, of HCFA:

September 4, 1984 memorandum To Stan Katz, Subject: Pacemaker Registry -- INFORMATION, From Frank Spruill, HCFA;

and

September 11, 1984 Note to Stanley Katz, Subject: Warranty Information in Cardiac Pacemaker Registry -- Your Oral Request at Meeting with FDA on 8/29/84, From Harold Fishman;

and

September 14, 1984 Note to Robert Wren, Acting Director, Office of Coverage Policy, Subject: Pacemaker Warranty Information for FDA's National Registry, From Allan Lazar, Director, Office of Medical Review, HCFA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care
Financing Administration

CONTROL, OPA

Memorandum

SIGN: JB
DUE: 10/19
CNO: 9410167855

① AG
② FD
③ JB

FYI
OPOP
DFO

Date OCT 13 1984

From Director
Bureau of Eligibility, Reimbursement and Coverage

Subject Handling of Claims Related to FDA-Recalled Medical Devices--ACTION

To See Below

High level Congressional interest has been expressed in what action HCFA is contemplating to recover Medicare benefits paid for expenses related to defective medical devices. We feel it is necessary to develop coordinated policies and procedures for dealing with this type of situation, and that this requires the active participation of several HCFA components as well as OGC. We would, therefore, appreciate the attendance of appropriate representatives from your office at a meeting on October ~~16~~ 23, 1984 to discuss this matter.

Pursuant to regulations, Medicare pays hospitals and physicians conditional payments for such expenses, subject to recovery from anyone who received payment from a liability insurer or from the manufacturer or its insurer. As indicated in Regional Letter 84-5 (copy attached), instructions are needed for identifying claims for replacement of medical devices, or other corrective procedures, in which conditional payments and possible recovery are called for. Various components have the expertise and responsibility for elements of the contractor instructions, e.g., billing and claims procedures, coding, coverage, reimbursement, reporting, as well as for developing and implementing plans for effecting recovery from liability insurance payments or recommending legal action against manufacturers and their insurers when indicated.

48567

Attached is a list of issues that we believe need to be addressed in developing operating instructions and HCFA's role. Pertinent background information is also attached. If you know of any additional issues, they should be raised at the meeting. *

Please have a representative call Israel Brauner, ext. 75139, who will provide information on the time and place of the meeting.

Henry R. Desmarais, M.D.

Attachments

Please call OPA, if anyone *
from your office
is interested in attending by 10/18
NOON.

Addresses:
√BPO
BQC
HSQB
OGC
OCP, BERC
ORP, BERC

Medicare Costs Related to FDA-Recalled Medical Devices

Issues

1. Is there an alternative (e.g., regulatory or instructional change, use of section 518(b) of Food, Drug & Cosmetic Act (copy attached)) to using the cumbersome liability insurance recovery method to recover costs related to FDA-recalled medical devices?

2. Under DRG reimbursement, is it useful to find out if providers get a credit from manufacturers of replaced devices for the device itself or services associated with repair or replacement? If so, is it feasible to require providers to exercise warranty rights before billing Medicare?

3. Can the expenses of additional monitoring attributable to the recall status of a device be readily identified? If so, is it administratively feasible to attempt recovery of such small expenses individually, cumulatively or in the aggregate?

4. Are physicians or others required to report more frequent than normal monitoring of patients with recalled devices such as cardiac pacemakers? If so, should carriers be instructed to inform intermediaries for hospitals in their contract areas when they do, since this can be a lead for recovery of payment for hospital services for repair or replacement of the recalled devices? (See attached letter to a carrier from a cardiac monitoring service.)

5. Can diagnostic and procedure codes be used to detect hospitalizations associated with repair or replacement of medical devices besides cardiac pacemakers? (See ICD-9-CM 996.0-996.5.) Is it possible to do anything on the Part B side for services related to replacing a device, e.g., surgeon's bills, even though similar coding may not be required on Part B claims?

6. What is the best way to get information on FDA-recalled devices to contractors to use in matching such recall notices against diagnostic and procedure codes on hospital bills? (See sample FDA Enforcement Report attached.) Are there operational or administrative reasons not to develop leads, e.g., the fact that since bills do not identify manufacturer, etc., development in many cases would be negative?

7. Are implementation instructions for Section 2304 (Pacemaker Review and Reform) of the Deficit Reduction Act pertinent? If so, how can they be used in connection with contractor and Regional Office instructions dealing with the recovery of Medicare benefits paid in connection with FDA-recalled medical devices? Is it statutorily permissible or feasible to develop a registry for devices besides cardiac pacemakers?

8. Who will handle the documentation of cases — a case may include a number of claims — for referral to Department of Justice through (we assume) Office of General Counsel? Who will make the formal recomendation for direct government action against the manufacturer or its liability insurer? Other administrative issues relate to staffing by Medicare contractors to handle the workload of processing, flagging, following up, etc. conditional payments.

9. What reporting mechanisms will be required to track amounts of recovery of payments for FDA-recalled devices?

10. Should "repayment agreements" be obtained from beneficiaries when conditional payments are made? If so, what criteria are needed for staff deciding whether to get them in a particular case?

fat callin
412 15

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Memorandum

Date OCT 16 1984

From Assistant Director for Intragovernmental Liaison, CDRH (HFZ-3)
Program Analyst, Division of Planning and Evaluation, CDRH (HFZ-30)

Subject Pacemaker Registry Implementation Strategy

To See Below

As you know, recent legislation requires that FDA provide for a registry of pacemaker and lead implantations for which payment is made under the Medicare program. Since the legislation was signed into law, the Center has assembled a Task Force to examine issues related to implementing the registry as specified in the legislation and make recommendations to Center management.

Attached is the Task Force's draft Pacemaker Registry Implementation Strategy paper for your review. Please refrain from editorial comments and concentrate particularly on the strategy, Office assignments, and recommendations. Please send your comments to Donna Lenahan, HFZ-30, T-515, by C.O.B. October 24. If you have questions, please contact Ms. Lenahan on 443-5807. Thank you for your cooperation.

Robert Eccleston
Jeanne Westcott for

Donna Lenahan
Donna Lenahan

Attachment

Addressees:
Robert Britain
Marlene Haffner
Joseph Arcarese
Neil Goldstein
Walt Gundaker
Roger Schneider
Marvin Rosenstein
Phil White

Task Force Members:
Glenn Rahmoeller
Walter Scott
Wendy Johnson
Janet Hardy
Fred Hooten
Les Weinstein
Robert Skufca
Kathy Schroeher

DRAFT

Cardiac Pacemaker Registry Task Force

Implementation Strategy for Pacemaker Registry - DECISION MEMORANDUM

Director
Center for Devices and Radiological Health
Through: Deputy Director, CDRH ______

PURPOSE AND SCOPE

This memorandum is intended to provide you, the Deputy Director, and other senior Center staff with: (1) the details regarding the recently enacted legislation which requires the Secretary through FDA to establish a national registry for cardiac pacemaker devices; and (2) options and recommendations for establishment of the registry, financial support for this activity, utilization of the data, and interrelationships with the Health Care Financing Administration (HCFA).

I should note at the outset that this strategy paper largely represents the ideas, opinions, and views of the Task Force. (At Tab A is a list of the Task Force members and the organizations they represent.) However, Task Force representatives have discussed this report in broad terms with their Office management, and this strategy paper has been shared with Center components for review. The memorandum is broken down into various sections and is modeled after the Agency's standard legislative implementation plan format. We did this in case the Department and/or PHS asks us to submit a formal plan, although indications are that no such request will be made.

TITLE AND PUBLIC LAW NUMBER: "Deficit Reduction Act of 1984" -
P.L. 98-369

DATE OF ENACTMENT: July 18, 1984

BACKGROUND ON THE ACT

Overall goal:

The primary aim of that portion of Section 2304 of the Act, "Pacemaker Reimbursement, Review, and Reform", relating to the pacemaker registry, is to assist the Department in determining when Medicare payment may properly be made for pacemaker device implants and re-implants, and in tracing the performance of these devices. A copy of the final wording of this section of the law is appended at Tab B.

One component, the second, [illegible] improve FDA's [illegible] of pacemaker [illegible] quickly.

Major thrusts of the Act:

Section 2304 of the new law contains two main components, both relating to Medicare reimbursement for pacemaker and pacemaker lead implants and re-implants.

1. The first major requirement under this section relates to current HCFA guidelines that prescribe specific intervals for post-implant monitoring for purposes of determining Medicare eligibility. The new law requires a revision of these guidelines in an attempt to curb billing claims for too frequent or unnecessary transtelephonic monitoring. This section also requires that the Department undertake a review of current Medicare payment schedules for physician costs, and that the Prospective Payment Assessment Commission (PPAC) review hospital charges associated with pacer implantations. Reports are due to the Congress by March 1985. Except for the review and report by the PPAC, it is clear that HCFA has sole responsibility for implementing these requirements.

2. The second major component requires the Secretary (through FDA) to "provide for" a registry of all pacemaker devices and leads implanted or removed on or after the effective date of implementing regulations for which payment was made under Medicare. The registry would include information such as the manufacturer, model and serial numbers, date and location of the implantation or removal, and any expressed or implied warranties. HCFA may deny Medicare payment in whole or in part if the required information is not submitted to the registry. Reimbursement may also be conditioned on the return by the providers of services of explanted devices to manufacturers, as well as the testing by manufacturers of such devices and the sharing of test results with the providers. (Providers are defined by the Medicare statute to be hospitals, nursing homes, home health agencies, and hospices.) In addition, FDA personnel are authorized to witness product testing by manufacturers.

   A January 1, 1985, deadline for establishing the registry and for developing the supporting regulations is specified in the statute.

SECTION-BY-SECTION ANALYSIS OF THE ACT

The following is a breakdown of the registry provisions of the Act under Section 2304(c) and (d). Subsection (c) amends Section 1862 of the Social Security Act by adding a new subsection (h):

- (h)(1)(A) States that the Secretary shall, through the Commissioner of FDA, provide for a registry of all cardiac pacemakers and leads implanted or explanted on or after the effective date of implementing regulations and for which payment was made under Medicare.

- (B) Specifies the type of information to be included in the registry and gives the Secretary discretion to require the submission of additional information.

- (C) Requires physicians and providers seeking Medicare payment for pacemaker/lead implant or replacement procedures to submit the specified information to the registry "in accordance with regulations of the Secretary."

- (D) Explains that the purpose of the registry is to: (1) assist the Secretary in making reimbursement decisions; (2) trace the performance of pacemakers and leads; (3) determine when inspections/testing must be performed by manufacturers as a condition for payment; and (4) carry out studies on the use of pacemakers and leads. (If studies are performed, the statute precludes disclosure of the identity of specific patients.)

- (E) Allows any individual or organization to report information to the registry with respect to pacemaker devices not reimbursed under Medicare.

- (h)(2) Gives the Secretary discretion to require by regulation that providers return explanted devices or leads to the manufacturer for testing, and to prohibit providers from charging any beneficiary unless this condition has been met.

- (h)(3) Gives the Secretary discretion to require, by regulation, that manufacturers test explanted devices and share test results and warranty information with providers. In cases where the Secretary believes that a device was replaced due to malfunction, the Secretary is also authorized to dispatch FDA personnel to observe manufacturer testing in order to confirm whether a particular device was functioning properly.

- o (h)(4) Authorizes the Secretary to deny Medicare payment unless the conditions noted above are met.

Subsection (d) concludes by setting a January 1, 1985 deadline for establishment of the registry and promulgation of final regulations, and requires the submission of data on procedures performed on or after the effective date of implementing regulations.

Attached at Tab C is an excerpt from the House-Senate conference report that describes Congressional intent.

HISTORY OF THE ACT

In order to better understand the specific requirements of the Act and the rationale behind them, a brief review the legislative history may be helpful.

Allegations of abuses in the pacemaker industry:

Public attention to abuses in Medicare's pacemaker financing program first came to light in a September 1982 report by the Senate Special Committee on Aging, chaired by Senator John Heinz (R-PA). The report, entitled, "Fraud, Waste, and Abuse in the Medicare Pacemaker Industry," was based on a year-long Committee staff investigation triggered by constituent complaints and reports of excesses in pacemaker sales practices.

In the report the Committee cited various concerns relating to pacemaker performance, cost, warranties, professional qualifications of implanting physicians, utilization, and allegations of criminal action. To address these concerns, the Committee recommended a number of remedial actions. With respect to FDA, the report called for: (1) mandatory reporting requirements for product failures; (2) greater assurance regarding the propriety of clinical testing procedures; and (3) the development of procedures for the evaluation of devices explanted from Medicare beneficiaries.

In addition to FDA, the Committee proposed a number of actions for HHS, VA, SEC, and for the Congress, including the enactment of legislation requiring either FDA or HCFA to establish a pacemaker registry. (This particular recommendation was no doubt based on the Committee's knowledge of FDA's pilot registry referenced in the report, which was initiated in 1974 and terminated in 1980. It should be noted that maintenance of this registry has been continued by the five medical centers which supplied information to the registry during its existence under FDA.)

Introduction of legislation:

Based on the foregoing report, Senator Heinz introduced the "Medicare Pacemaker Payment Reform Act and Patient Protection Act" (S. 1622) in July 1983. In addition to calling for a review of hospital and physician charges associated with pacemaker implant procedures, the bill called for the formation of a national pacemaker registry under the aegis of FDA. In the rationale for this proposal, Senator Heinz noted the completion by FDA of a "successful pilot pacemaker registry program." He added that "[A] registry would help track the performance of pacemaker devices... so that premature failures can be discovered in a timely fashion and appropriate protection steps taken..." "The registry will be used by pacemaker professionals as a source of research data for a variety of studies which can improve the quality of care offered to Medicare patients..." and "... the registry will achieve some cost savings by allowing a more accurate warranty monitoring system, which will partly offset the estimated $1 million annual cost of maintaining the registry."

At the same time, Congressman Ron Wyden (D-OR), introduced a virtually identical bill in the House (H.R. 3590, the "Medicare Pacemaker Payment Reform and Patient Protection Act").

No legislative hearings were held on either of the two measures, but debate was held at the Committee level as efforts were made to incorporate versions of each bill into other budget-related legislation. Differences between House and Senate versions were negotiated during conference committee deliberations. Issues that were agreed upon included: (1) the adoption of House language that FDA "provide for" a registry, as opposed to "establish", as in the Senate bill; (2) the elimination of a manufacturer reporting requirement relating to adverse effects associated with pacemakers and leads to avoid duplication of reporting under the Agency's impending MDR regulation; and (3) the deletion of a requirement to have manufacturers post a bond or provide other assurances to ensure compliance.

HHS position on pacemaker registry legislation:

Throughout Congressional consideration of the registry bills, no formal HHS position was sought. However, through informal Departmental channels and in face-to-face meetings with Congressional staff, FDA questioned the feasibility of the proposals on two grounds: (1) the primary goal of the bills was cost-containment and therefore should be administered by HFCA; and (2) the imposition of a new requirement on FDA without a corresponding authorization would seriously hamper the Agency's attempts to fully comply with this new mandate as well as our overall responsibilities under the Medical Device Amendments.

FDA was not alone in its opposition to the legislation within the Department. In a letter dated October 21, 1983, to the Chairman of the Senate Aging Committee, HCFA Administrator Davis indicated that the enactment of a new hospital prospective payment regulation, the issuance of guidelines for Medicare contractors on the medical necessity for pacemaker implants, and HCFA's intent to provide for a 100 percent review of pacemaker claims, would go a long way in curtailing the high costs to Medicare of pacemaker procedures.

CURRENT HCFA PROCEDURES FOR PACEMAKER REIMBURSEMENT

HCFA's procedures for Medicare and Medicaid reimbursement underwent drastic changes with the implementation in FY 83 of the Diagnostic Related Group/Prospective Payment System (DRG/PPS). Under this system, HCFA has established levels of reimbursement to hospitals for diagnoses and treatment of conditions according to a complex classification scheme and formulas. Hospitals know in advance how much they will be reimbursed on a per-patient basis for treating a given condition. If a hospital's actual expenses for treatment of a particular patient are greater, the hospital must absorb the difference. If actual costs are less, the hospital can keep the difference. The DRG/PPS provides a built-in incentive for hospitals to reduce their costs and carefully consider the benefits of diagnosis and treatment programs relative to their costs.

Hospitals typically keep an inventory of pacemakers on consignment from manufacturers. It was the hospitals, then, that requested reimbursement for the cost of the pacemaker under the old Medicare system. Under DRG/PPS, hospitals no longer request reimbursement for the device specifically, but for the entire treatment program (excluding physicians' fees), of which the pacemaker unit is only a part. Consequently, the concern over the cost of the pacemaker has shifted from HCFA to the hospitals. The same is true for warranties. It is now in the hospital's interest to exercise warranty coverage when replacing failed pacemakers and leads. In the future, HCFA may consider adjusting its reimbursement formula for replacing devices under warranty, but it is not something that is done currently.

Under the DRG/PPS, HCFA requires hospitals to contract for Professional Review Organizations (PROs) to review Medicare and Medicaid cases for medical necessity, appropriateness, and quality of treatment, based on information provided in the patient's medical records. In response to allegations in the Heinz report on pacemakers, HCFA (as noted earlier) has initiated 100 percent review of pacemaker implantations. The PROs are also collecting whatever warranty information is available to them and are instructing hospitals to include warranty information on charts when available.

UTILIZATION OF DATA BY FDA AND HCFA

It is estimated that approximately 120,00 pacemaker implantations and 30,000 lead replacements will be reported to the registry per year. These numbers can be expected to increase annually as the nation's elderly population increases. Each registry record may contain as many as 20 data elements.

FDA's responsibilities under the Act regarding use of pacemaker registry data are stated in Section 2304(c), i.e., "...tracing the performance of cardiac pacemaker devices and leads, in determining when inspection by the manufacturers may be necessary under paragraph 3, and in carrying out studies with respect to the use of such devices and leads." With this mandate in mind, the Task Force compiled the following list of data elements it believed would be necessary for FDA to perform these tasks.

o Data Elements Required by the Act:

  - manufacturer name;
  - model and serial numbers of pacer or lead;
  - name of recipient of pacer or lead;
  - date and location of implantation or removal of pacer or lead;
  - name of physician implanting or removing pacer or lead;
  - name of hospital or provider billing for the procedure; and
  - express or implied warranties associated with the device or lead.

o Additional Data Elements Necessary to Support Problem and Use Trend Analysis:

  - whether the procedure is an initial implant or a replacement; and
  - for explants, whether the provider believes the explant is possibly, probably, or probably not, device-related.

- Data Summaries and Reports:
  - the Task Force believes the registry system should have the capability of searching the data by certain keywords and not others, e.g., keywords that might reveal confidential information;
  - keywords and phrases we would definitely want to search by include:
    - manufacturer
    - model number
    - serial number
    - date of procedure
    - possibly device-related explant
    - probably device-related explant
    - probably not device-related explant
  - actuarial analyses, i.e., failure and survival rates for given manufacturer, model number, or serial number for various time intervals (1-6, 7-12, 13-18, 19-24 months) and overall.

The pacemaker registry legislation does not mandate that adverse experience data be provided to the registry. The reason provided in the legislative history is that the new MDR will require such information. However, MDR (and DEN) are not comprehensive experience reporting systems. Therefore, any adverse experience information that can be derived from the registry (i.e., performance trends) should be made available to those responsible for evaluating MDR/DEN data so that a complete picture of device performance can be obtained. However, since the basic purposes of the three systems (adverse experience reporting versus cost-containment), the circumstances under which reports are made, and the reporting base differ, the Task Force recommends that the registry be maintained separately.

The pacing profession in the U.S. has for years been interested in the establishment of a registry of this type for research purposes, traceability, and device performance monitoring. With the establishment of this system it is likely the profession and perhaps other government agencies will express a need for certain data that could be derived from the registry. At this time the Task Force cannot anticipate what all of these needs might be, but believes that there would be value in reasonably trying to meet them. Therefore, the system utilized to collect and analyze the registry data should be amenable to making modifications as the need arises and sharing that data.

The Bureau of Eligibility, Reimbursement, and Coverage (BERC), HCFA has indicated the following data needs for HCFA to perform its responsibilities under the new legislation:

- notification by FDA of product recalls by manufacturer, model number and serial number; and
- notification of reimplants.

The BERC would use this information to determine whether to pursue reimbursement under certain circumstances from manufacturers of pacemaker devices.

Correspondence between the Task Force and BERC officials regarding registry implementation is contained in Tab D.

POSSIBLE MODELS FOR THE PACEMAKER REGISTRY

There are several past or currently operating systems for collecting the kind of information about pacemakers that the recent legislation will require FDA to collect. If any one of these systems was as comprehensive as the legislation requires, FDA could simply purchase that data. Unfortunately, all existing systems are voluntary and, as best as could be determined, are not nearly as specific and comprehensive as is necessary to fulfill the requirements of the law. In their present form, they may only serve as models to guide the development of our own registry.

FDA Pilot Registry:

FDA's pilot registry (1974-1980) was implemented to gather safety and performance data on a variety of pacemaker makes and models. Five pacemaker centers followed over 8,000 pacemakers. Leads were not registered until the last two years of the registry. The registry collected detailed medical history and patient followup data (until the death of the patient or explant of the pacemaker), in addition to the type of data that will be required in the new registry. Although the primary purposes of the two registries are different, the experience of the earlier registry will be valuable in establishing the new registry. The pilot registry was maintained for six years at a total cost of over one million dollars.

The individual physicians who participated in FDA's earlier registry have continued to collect data. This data is periodically published in *PACE*, the journal of the North American Society for Pacing and Electrophysiology (NASPE). One of these physicians has expressed an interest in participating in the development of the registry.

The National Implant Registry:

ECRI (formerly the Emergency Care Research Institute) is a non-profit organization devoted to improving patient care through scientific, technical, and educational programs related to the delivery of health services.

Its primary task is the assessment of health care technology. ECRI represents the user, the hospital, the health care professional, and the patient, i.e., those who ultimately pay the cost of medical devices and the penalties for their deficiencies.

ECRI operates the National Implant Registry (NIR). The NIR, which was established in 1982, is a service offered to health care providers (primarily hospitals) that:

- maintains central, computerized records of patients, implants, hospitals, and physicians;
- matches records against recall notices and product warnings;
- alerts hospitals and physicians to defects and deficiencies;
- traces patients to facilitate future contact and corrective action if an implant proves defective; and
- provides consultation services.

The cost for the service ranges from $16.50 to $24.40 per implant, depending on the number of implants per institution. An active subscription effort has only recently begun. At present, fewer than one percent of hospitals subscribe to NIR. The president of ECRI has expressed an interest in participating in the development and maintenance of this registry.

Tab E contains several letters from individuals interested in assisting FDA in establishing and maintaining the registry.

The Veterans Administration Pacemaker Surveillance System:

In 1981-82 the Veterans Administration (VA) established a nationwide Pacemaker Surveillance Program. The purpose of the program is to provide transtelephonic monitoring of pacemaker patients and cardiology consultation to referring (VA) medical centers in a timely manner. The Pacemaker Center's services include:

- transtelephonic monitoring of patients;
- alerts to referring physicians of patient condition and problems;
- 24-hour coverage for pacemaker emergencies;
- scheduling of routine transtelephonic checks for each patient; and
- maintenance of a computerized data base for analyses and furnishing of certain reports to referring medical centers.

The Pacemaker Center also tests explanted pacemakers to confirm suspected failures.

The Pacemaker Surveillance System currently registers 10-15,000 patients throughout the country, most of whom received their pacemakers at VA hospitals. The data management and computer operations aspect of the system are managed by the individual pacemaker centers. Start-up costs for the East Coast Center were $250-300K. Annual maintenance requires approximately 4-6 staff people and $70-80,000 (excluding salaries).

The Director of the Pacemaker Center has offered his cooperation in establishing this registry, and the computer software which the VA has developed.

IMPLEMENTATION OPTIONS AND ORGANIZATIONAL ROLES

This section discusses two aspects of registry implementation; (1) how the registry should actually be maintained; and, (2) which organizations should be responsible for performing registry-associated tasks.

There appears to be three options for establishing and maintaining the actual pacemaker registry data base, which includes: data collection, review, and editing; data entry; and system design and programming.

- In-House Effort:

The most obvious option is for the Center to establish the registry in-house. To do so would require the following estimated resources annually:

Task	Staff Yrs.	Funds
Data collection, review, editing	3.0-4.0	-----
Data entry	3.0	$100K
System design & programming	0.5	-----
System hardware		$ 50K
	6.5-7.5	$150K

The total estimated dollar cost of maintaining the registry data base in-house would be approximately $450,000 per year (assuming $40,000 per staff year).

o Extramural Contract:

The second option is to contract for establishment and maintenance of the registry. A number of individuals have already expressed an interest in assisting FDA in this manner. A consultant experienced in establishing and maintaining a data base of similar size estimated the registry would cost from $450-750,000 per year, depending on the complexity of the system.

o HCFA:

A third possibility might be to utilize HCFA's PRO system to collect the registry data (most of the required data is already being collected by PROs). HCFA could then send periodic reports to FDA for trend analyses. This option may require some transfer of funds from FDA to HCFA to amend HCFA's contracts with the PROs to include collecting the additional data. HCFA staff are currently exploring the feasibility of this approach. If possible, the Task Force recommends this as the option of choice for implementing the registry. If utilizing the PRO system (or another of HCFA's data collection systems) is not possible, the Task Force recommends a contract effort.

Although a contract effort may be more costly than maintaining the registry in-house, the Center does not have the staff years necessary to devote to the registry without eliminating other projects. The Center will also have to implement MDR, a data base of undetermined size and complexity, in the near future. In addition, establishing the registry under contract would be in keeping with OMB's Circular A-76, which encourages agencies to contract for services whenever possible.

The Task Force believes these other registry-related tasks would most appropriately be distributed in the following manner:

Activity	Lead Organizational Component(s)
1. Formation of FDA/HCFA coordinating committee to oversee implementation of the registry	Pacemaker Registry Task Force
2. Pursuit of support options, including IAG/MOU	OMS/OCD
3. Development of regulations	OSP
4. Contract monitoring	OMS/ODE
5. Summary data evaluation	ODE
6. Investigation/followup	OC
7. Educational initiatives to inform providers and manufacturers of their new responsibilities under the law	HCFA/OTA

8. Report distribution	OMS
9. Interface with HCFA (post-implementation)	OMS /ODE
10. FDA observation of testing	OC/OST

FUNDING OPTIONS

Upon signing of the "Deficit Reduction Act" by the President, the Senate Committee on Appropriations, in its report on the FY 85 appropriations bill, stated that "... the Committee will expect FDA to assess the need for additional staff years and submit a supplemental appropriation request sufficient to meet that need." FDA's Division of Financial Management (DFM) presently is preparing a supplemental request to the FY 85 budget for 11 FTEs and $1.2 million to support implementation of the registry. (DFM's estimate was based on one of the proposed versions of the registry bill that included FDA testing of devices, and which was estimated to be much more costly than the final bill.) The FY 85 budget has been passed by the House and Senate and is currently awaiting conference. The procedures for making a supplemental request are basically the same as those for making the original budget request and equally lengthy. Therefore, it will be some time before a decision is handed down on the supplemental request. In the meantime, the Center must move ahead with implementation plans in order to demonstrate to Congress our intent to implement the registry in a timely fashion.

While the FY 86 budget request did not address resources to implement the pacemaker registry (it was prepared before the bill was signed into law), informal communications between DFM and the Department have indicated that the Agency will have to absorb the needed resources. However, DFM is including the 11 FTEs and $1.2 million in its appeal of the Department's budget mark for FDA (the limit on what we may ask for in our budget to OMB).

The Task Force considered the Center's pursuing the following funding options to support the pacemaker registry.

- Interagency Agreement (IAG) with HCFA: Regardless of the preferred implementation option, the Center should pursue an IAG between CDRH and HCFA's Bureau of Eligibility, Reimbursement, and Coverage (BERC) to clarify organizational roles and expectations, and to transfer necessary resources to the implementing agency. Before an IAG is formalized, an informal agreement on the particulars needs to be reached between the Center Director and the Director of BERC. If the two agencies cannot agree on the direction of transfer and level of resource support, an IAG will not be a viable option. At the very least, however, the two agencies should develop a memorandum of understanding reflecting respective roles and expectations, but with no transfer of resources.

- Cost-Sharing Contract: If it is decided that the registry should be maintained by an outside contractor, an option may be to allow the contractor to sell data summaries and reports (provided confidentiality of certain information is maintained) to defray some of the costs of the contract. This approach has been presented to FDA's Division of Contracts and Grants Management and, while they have no direct experience with such an arrangement, they knew of no obvious reason why it might not be possible.

TIMETABLE FOR SPECIFIC IMPLEMENTATION STEPS

Interagency Agreement: Experience indicates that formalizing an IAG can take from three to six months from the time the document leaves the Center for various approvals and sign-offs. This is in addition to the time required to negotiate an informal agreement and prepare the documents. Once the document leaves the Center it must go to FDA's Office of Health Affairs, the Office of Regulatory Affairs, the Division of Financial Management,OMO, and the Division of Grants Management, OMO, for signature. Keeping these Offices informed early-on in the development of the document may shorten the three to six month time frame.

From the Division of Grants Management the document must go to HCFA for sign-off. HCFA staff have indicated that if the appropriate offices are also kept up-to-date on the progress of the IAG, HCFA review and sign-off could be accomplished within one month.

Regulations Development: At this point it is still undetermined how the regulations development tasks will be divided between FDA and HCFA. In any case, the Task Force is recommending that FDA develop just one regulation that includes both the mandatory and optional aspects of the bill rather than promulgating a number of regulations. The following steps are required to promulgate a regulation:

- Preparation of notice of proposed rulemaking
- Preparation of SF-83 Request to Collect Information
- Center review, revision, and sign-off
- FDA sign-off (ACRA, GC)
- Department sign-off
- OMB review

- Publication in the Federal Register
- Comment period
- Review comments, prepare preamble, final rule
- Center review and sign-off
- FDA sign-off
- Department sign-off
- OMB review
- Publication in Federal Register

Currently, the Center's FY 85 regulations plan estimates that a proposed rule will be out-of-Center by June 1985 and out-of-FDA by September. The promulgation of a regulation implementing the pacemaker registry has been assigned priority three.

Extramural Contract: Contracting for the establishment and maintenance of the registry may require a minimum of four to six months until award of contract. The following steps are involved and require close coordination with FDA's Division of Contracts and Grants Management:

- Appoint Project Officer, Project Advisory Group
- Prepare Memorandum of Need
- Prepare Request for Proposal
- Receive bids
- Evaluate proposals
- Award contract

NEED FOR AN ADVISORY/COORDINATING COMMITTEE TO OVERSEE IMPLEMENTATION

When the Task Force was organized, it was decided that its mandate--at least initially--would be limited to researching and discussing registry implementation issues and options, and presenting these with recommendations to Senior Center Management. The Task Force had not envisioned its role going beyond that mandate. The Task Force agrees, however, that there will need to be some group whose job it is to coordinate and oversee actual implementation of the registry, including interfacing with HCFA and FDA staff. There also needs to be a mechanism by which the opinions and concerns of groups outside government who have an interest in the registry (e.g., health professionals, manufacturers, insurers, consumers) can be heard. The question is, then, how to satisfy these two needs.

Should the Task Force continue and serve the advisory and coordinating functions?

The Task Force thinks not, at least with its present composition. A coordinating committee should be composed of representatives of those organizations that will most appropriately have hands-on involvement in implementing the registry, particularly HCFA. In its present composition the Task Force represents only FDA. Most likely, some, but not all, Task Force members will appropriately become part of the coordinating committee. Its composition, however, should be influenced by the decisions made as a result of this options paper.

Should the coordinating committee include representation outside of FDA and HCFA?

The Task Force believes the coordinating committee should include representation only from within FDA and HCFA. The purpose of the coordinating committee should be to oversee implementation of the registry. Admittedly, considering the advisory opinions of outside groups will result in a more useful and beneficial system. However, FDA will be under close Congressional scrutiny regarding the registry. Implementation could be severely hampered by an impasse between representatives of conflicting outside groups.

Should a separate advisory committee be established to make recommendations to the coordinating committee?

Establishing a new advisory committee is a very lengthy and expensive process. The Task Force believes that ample representation from outside groups can be obtained through the Cardiovascular Devices Panel and opportunities for public input through the administrative rulemaking process. The Cardiovascular Devices Panel includes health professional, industry, and consumer representation. In addition, organizations representing these constituencies monitor the Federal Register and the scheduling of panel meetings and public hearings on issues of interest to them. FDA may also contact specific groups, e.g., the American College of Radiology, to solicit their comments and attendance at a meeting.

IMPACT OF THE REGISTRY REQUIREMENTS ON EXISTING LEGISLATION/REGULATIONS

The Task Force reviewed the Medical Device Amendments and existing regulations for the potential for impact or conflicts between them and regulations necessary to implement the registry law. The following potential interrelationships were identified.

- o Section 820.198 of the GMP regulation requires investigation and records of complaints regarding the possible failure of a device by the manufacturer. Return of explanted pacemakers could be interpreted as a complaint. Section 820.198 will need to be taken into consideration if regulations pertaining to the return of explanted pacemaker devices to manufacturers for testing are promulgated.
- o The recently promulgated MDR regulation requires reports and investigations into device failures which cause or have the potential to cause death or serious injury. Certainly failures of pacemaker devices would fall into this category. When promulgating the registry regulations, the Center must consider and address any overlap with MDR.
- o Any regulation promulgated to implement the registry should specifically address pertinent FOIA issues. If FDA obtains data from HCFA, FDA will need to know of any HCFA regulations that might affect releasability of the data.

CONGRESSIONAL EXPECTATIONS

In an August 13, 1984 meeting with Senate Aging Committee staff, FDA representatives were advised that, despite the departure of a key Committee staffer who was the principal architect of the registry legislation, interest in this matter on the part of Senator Heinz will not diminish. At that meeting, it was noted that compliance with the January 1, 1985 statutory deadline is very unlikely. We were advised, however, that oversight hearings might be held by the Committee after the new Congress convenes in 1985, at which time substantive evidence of progress would be expected. FDA will provide the Committee with a status report of the Agency's implementation plans on or about the first of the year.

Recently, the Secretary has received inquiries from Congressman Dingell and Senator Proxmire, both of whom expressed concern over Medicare payment for defective medical products under warranty with particular emphasis on pacemakers and pacemaker leads. Copies of these letters and the Secretary's response are contained in Tab F.

The Secretary is currently pursuing recovery from Medtronic for Medicare payments for replacement of defective pacemaker leads under the liability insurance provisions of Medicare law, which appears to be the Department's only recourse in such cases. Whether the registry will be useful as a cost-cutting tool by identifying major product failures and providing warranty information remains to be seen.

IMPLEMENTATION STRATEGY

The Task Force believes that registry implementation activities can be grouped according to the sequence or time frame in which they should be initiated or undertaken. Viewing registry implementation in steps helps us to take an integrated look at the various tasks. It also serves to separate the various tasks into manageable groups on which effort can be focused at the appropriate time.

The Task Force recommends proceeding with registry implementation in these phases:

- Phase I - advise Commissioner/Deputy Commissioner of CDRH actions and decisions regarding implementation (OCD/OMS)
  - form FDA/HCFA coordinating committee (Task Force)
  - explore data collection by HCFA (OMS)
  - solicit input from affected groups (ODE)
  - determine data needs, format (Coordinating Committee)
  - initiate IAG/MOU process - determine responsibilities and expectations of the two organizations (OCD/OMS)
- Phase II - initiate regulation promulgation (OSR)
  - initiate contract process [if necessary] (OMS)
  - prepare progress report to Commissioner, Congress (OCD/OMS)
- Phase III - publish proposed regulation (OSR)
- Phase IV - educational initiatives (HCFA/OTA)
  - publish final regulation (OSR)

The Task Force anticipates that Phase I could be accomplished during the first quarter, FY 85; Phase II, during the second quarter; Phase III, during the fourth quarter; and Phase IV, during the second quarter FY 86.

CDRH SENIOR STAFF COMMENTS - to be completed

SUMMARY OF RECOMMENDATIONS

The following summarizes the Task Force's major recommendations for implementing the pacemaker registry.

Concurrence

1. OCD should inform the Commissioner of our action plan and steps taken thus far, followed up with a more substantive progress report to both Congress and the Commissioner (sample memo attached at Tab G).

Concur ________

Nonconcur ______

2. FDA/CDRH should approach HCFA concerning an IAG or MOU whereby HCFA's PROs collect the additional data needed to fulfill the registry requirements.

Concur ________

Nonconcur ______

3. If the PRO or other HCFA system cannot be utilized to collect the registry data, the Center should contract for the registy, preferably a cost-sharing type of contract.

Concur ________

Nonconcur ______

4. FDA should promulgate one regulation encompassing all aspects of the registry requirements for which FDA has lead authority. We should solicit input from HCFA where appropriate, however, the complexities of developing a regulation with another agency could be such that would prohibit that approach.

Concur ________

Nonconcur ______

5. A Coordinating Committee should be established within the Center with representatives from FDA and HCFA to oversee implementation of the registry. Input from outside groups should be obtained through the Cardiovascular Devices Panel meetings, comments to proposed regulations, and solicitation of select groups by FDA.

Concur ________

Nonconcur ______

6. FDA should consider the experience of other registry systems in establishing data needs and methods for obtaining and analyzing the data.

Concur ________

Nonconcur ______

7. The registry should be separate from DEN and MDR, however, there should be communication among the management of the three systems regarding problem trends.

Concur ________

Nonconcur ______

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

Health Standards and Quality Bureau
1849 Gwynn Oak Avenue
Baltimore, Maryland 21207

Hale

OPA

OCT 26 1984

NOTE TO John C. Berry

SUBJECT: Processes for Obtaining Data to Implement Pacemaker Registry Required by Section 2304 of P.L. 98-369

This is in response to your memorandum requesting our views on incorporating the processes for reporting to the pacemaker registry in the medical review and PHDDS processes.

At the present time, utilization and quality control peer review organizations (PROs) are required to report to HCFA the number of permanent cardiac pacemaker implants and reimplants reviewed and the number that are denied on the basis of medical necessity and appropriateness of the procedure. In addition, PROs are required to collect warranty information when a pacemaker reimplant is performed. Attached is a copy of the Pacemaker Reimplant Warranty Information report which is submitted monthly to HCFA.

In order to provide the information necessary for the national registry, PROs would have to collect and report more information than currently required in PRO contracts. Modification of the contract and more funding would have to be provided to PROs in order to have them obtain the necessary information. In addition, the accuracy of the warranty information obtained by PROs is questionable. PRO information gathering on pacemaker warranties is confined to the patients' chart, including the discharge summary. Therefore, inaccuracies recorded by the physician (or hospital) on the patient's chart or discharge summary would be reflected in the PRO's report. Mistakes could also be made in the transfer of information from PROs to HCFA and then to the Federal Drug Administration's (FDA) registry.

In the interest of efficiency and accuracy, I believe that physicians and providers should report cardiac pacemaker information directly to the FDA. This will make the physicians and providers more responsible for what they report.

I do not believe that pacemaker warranty information should be collected by PROs who themselves do not need this information to make review decisions or to perform any of their review activities.

Philip Nathanson
Director

Attachment

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OFFICE OF THE DIRECTOR

NOV 1 A9:25

PACEMAKER REIMPLANT WARRANTY INFORMATION

PRIOR INSERTION DATA			REIMPLANT DATA		
DATE OF INSERTION	PACEMAKER NAME/SERIAL NO.	WARRANTY PERIOD	DATE OF INSERTION	PACEMAKER NAME/SERIAL NO.	WARRANTY PERIOD

% OCP 10/29

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care
Financing Administration

Memorandum

Date

From Director
Bureau of Eligibility, Reimbursement and Coverage
Health Care Financing Administration

Subject Implementation of Pacemaker Provision (Section 2304) of the "Medicare and Medicaid Budget Reconciliation Amendments of 1984"—INFORMATION

To Mr. Robert C. Eccleston
Assistant Director of Intergovernmental Liaison
Center for Devices and Radiological Health
Food and Drug Administration

The purpose of this memorandum is to confirm certain understandings reached between Mr. Katz of my staff and you regarding our agencies' respective areas of responsibility for subsection (c) of section 2304.

Subsection (c), the registry provision, consists of two separate programs—(1) the establishment by FDA of a pacemaker registry, including the imposition of a reporting requirement on Medicare providers and suppliers (1862(h)(1)(A) and (B)), and discretionary authority to make Medicare payment for initial implants and replacements conditional upon compliance with the registry requirements, (1862(h)(1)(C) and (h)(4)(A)), due h by January 1, 1985; and (2) discretionary authority (1862(h)(2), (3) and (4)(B) and (C)) to deny Medicare coverage and payment to providers for pacemakers or leads not submitted for inspection and testing to the manufacturer, if so required.

We have agreed that, while the establishment and maintenance of the registry is clearly delegated to the FDA, HCFA would be responsible for rules with respect to the provision's impact on providers and physicians under Medicare. One Medicare provision ((h)(1)(C)) related to the registry is mandatory—physicians and providers are required to supply information to the FDA for the pacemaker registry for both initial implants and replacements. Another provision, (h)(4)(A)), although prefaced by a discretionary "may," enforces the mandatory provision by authorizing withholding of payment to physicians or providers who fail to submit information to the registry. While this latter provision is discretionary, we think it should be put into regulations. Although we already have broad regulatory authority to withhold payment to providers and suppliers who do not comply with various reporting requirements, we think enforcement of the new registry provision should be supported by a discrete regulatory provision that authorizes the withholding of Medicare payment when the reporting requirement is not complied with.

With regard to the discretionary inspection program, section 1862(h)(2) of the Medicare law will now permit the Secretary to: (A) require providers to return to manufacturers for testing any pacemaker or lead implanted or replaced; and (B) not charge beneficiaries if the devices have not been returned. Section 1862(h)(3) permits the Secretary to: (A) require manufacturers to test the devices (presumably at the manufacturer's expense); and (B) report the results to the provider, together with any warranty information, and require that FDA personnel be present at the testing if it is suspected that the pacemaker or lead had malfunctioned. Section

1862(h)(4)(B) and (C) permit the Secretary to deny payment under Medicare if the provider or the manufacturer fails to perform any of its responsibilities under this provision.

Although the enforcement provisions of section 1862(h) have clear implications for Medicare coverage and reimbursement for services, they are dependent for their application on the nature and efficacy of the proposed FDA pacemaker registry. Thus, development of HCFA's portion of the necessary regulations will be largely dependent on FDA action in this area. Consequently, we agree that responsibility for development of those regulations be jointly held by FDA/HCFA, with FDA the lead agency. HCFA would be responsible for supplying to FDA the necessary conforming regulations to Title XVIII with regard to 1862(h)(1)(C); (h)(2)(B); (h)(4)(A), (B) and (C) for inclusion by FDA with its regulations establishing the pacemaker registry.

We also wish to inform you that we plan to defer development, or at least publication, of regulations dealing with the portion of 1862(h)(2)(B) and (h)(4)(B) and (C) which would deny payment under Medicare in cases in which providers or manufacturers fail to submit pacemakers for testing if ordered to do so. This provision is couched in the discretionary "may." In addition, it obviously requires more extensive consultation and preparation than the registry provision. Moreover, its implementation and degree of specificity will depend on the actual functioning (not just regulatory requirements) of the pacemaker registry. The legislation seems to imply that some experience with the actual operation of the registry is expected, since it refers to information received from the registry as a basis for requiring that FDA personnel be present at the testing of a pacemaker or lead.

Our current pacemaker activities may well affect how this provision may be developed. These activities include the ultimate disposition of the Medtronic lead issue and the data and actions flowing from Professional Review Organization (PRO) 100 percent review of Medicare claims for pacemaker implants. It is possible that these activities will reduce or eliminate the need for any elaborate regulatory provision in this area. Consequently, we decided that at least the Medicare portion of this provision should be deferred until such time as we have a clearer view of what will need to be done and how the registry will affect our ability to do it.

We would appreciate your reaction to these plans and understandings. If you have any questions or alternative suggestions or recommendations, please contact Mr. Stanley Katz of my staff as soon as possible. (He can be reached by telephone at 594-8561.) If you agree that these plans and understandings are reasonable and feasible, please consider this memorandum to be an informal understanding between our two agencies as to how we will proceed.

Henry R. Desmarais, M.D.

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Memo of Meeting with HCFA Staff on Pacemaker Registry

November 16, 1984

Participants:

CDRH	HCFA
Bob Eccleston, OCD	Israel Branner
Glenn Rahmoeller, ODE	Ron Milhorn
Donna Lenahan, OMS	Madeline Ulrick
Kathy Johnson, OMS	Frank Spruill
	Bill Rush
	Michelle French
	Karen Haas
	John Burke
	Mr. Cavanaugh

This meeting was requested by Bob Eccleston. It is the second meeting with HCFA staff on the pacemaker registry. The purpose is to discuss alternatives for collection of registry data by HCFA.

Bob Eccleston opened the meeting by stating that HCFA staff had informed CDRH staff that the PRO system, which was considered as a potential data collection system for the registry, was no longer an option. Discussion turned to the use of HCFA's intermediary network to collect the data.

Frank Spruill stated that HCFA has contacts with approximately 60 intermediaries who process Medicare claims and they already have much of the data we need. They could be instructed to go back to hospitals performing pacemaker procedures to collect any additional data.

There was considerable discussion about how HCFA would implement the non-payment aspect of the law, since payments will already have been made by the time registry data gets to us. There was also discussion of what portion of the DRG payment for the event would be withheld. Neither of these questions was resolved.

Michelle French suggested proposing an interim final regulation to save the time required to promulgate a proposed rule. (Subsequent inquiries of CDRH staff indicated this approach would not be acceptable to FDA's General Council.)

Kathy Johnson, Frank Spruill, and Madeline Ulrick discussed what form the data from the intermediaries would be in, how it would be transmitted to FDA, and what kinds of analyses they would need. They indicated that the data would be transmitted electronically or on tape and that FDA would have to assemble the basically event-related information on a patient basis.

All agreed that we needed to finalize a list of data elements to be collected under the registry.

Madeline Ulrick, coordinator of the project within HCFA, stated she would draft a letter for Henry Desmarais' signature (Director, BERC) to John Villforth stating the agreements that had been made and opening up formal communication between our two organizations.

MEETING REPORT

SUBJECT: Implementation of Pacemaker Registry Provision

TIME AND PLACE: November 16, 1984, 9:00 - 12:30; 2nd Floor, Oak Meadows Building

ATTENDEES:
Bob Eccleston
Glenn Rahmoeller
Donna Lenahan
Kathy Johnson, FDA
Frank Spruill
John Burton
Gary Kavanagh
Faith Ashby, BPO
Michelle French
Karen Haas,
Bill Rush, Regs Staff
Israel Brauner, OEP
Ron Milhorn, OCP.

SUMMARY:

This meeting, originally billed as a technical discussion of the data elements required for the registry and how to obtain them, developed into a much broader discussion of the content, timing and respective agency responsibilities for the regulation.

Frank Spruill stated that data collection for the registry will be made through Part A intermediaries, not PROs, as originally suggested. Frank would also like to state somewhere that payments made are conditional, subject to compliance with registry requirements. Both at the meeting and in discussions beforehand, OCP assisted BPO systems in determining the amount and type of data fields needed for the form intermediaries will be required to complete.

In response to Regs Staffs queries, FDA said that they had discussed the implementation of the provision with Senator Heinz's staff and were told that, while rapid progress was expected, missing the January 1, 1985 effective date would not cause problems. Bob Eccleston will be writing to Stan Katz requesting assistance in drafting a joint FDA/HCFA letter to the Senator outlining progress and prospects for implementation of the provision.

FDA also wishes to come to an understanding on respective agency responsibilities. Ron Milhorn told them of the memo in clearance that seeks to do that. Bob Eccleston said they would review the memo with that in mind, and agreed that such an informal arrangement would be sufficient as far as he was concerned.

Ron Milhorn

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① FD
② AG
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OPOF

NOTE TO: OPOP

SUBJECT: Pacemaker Registry--ACTION

This strikes me as an open issue on which we need to reach a consensus and be certain our contractors are properly instructed on implementation. I frankly don't have a notion on what's right.

You should discuss this with OLP and HSQ and prepare either a decision memo or a contractor instruction. Let me know what you are going to do, please.

John C. Berry
John C. Berry

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Note To: John C. Berry ✓

Subject: Status of Legislative Proposal on Pacemakers (Your request of November 13, 1984)—INFORMATION

Your note requested the status of the subject legislative proposal. We have been informed by Office of Legislation and Policy staff that Patrice Feinstein has approved the A-19. However, it is to be submitted to the Administrator in conjunction with a decision memorandum on a collection mechanism for Medicare to use if a medical device is recalled. We understand that this memorandum is being written by the Office of Eligibility Policy in The Bureau of Eligibility, Reimbursement and Coverage.

A decision on how to proceed on this issue could have a substantial impact on the Medicare Secondary Payer workload. If a decision is reached to attempt collection for all recalled medical devices, MSP will be used as the recovery authority. This would entail collecting information on devices, compiling case histories for transmittal to the Department of Justice and following up on law suits/collection action. One of the decisions which the Administrator will be making is the organizational placement of the activity. We know that BERC believes it should be placed in BPO.

We shall keep you informed.

for John W. Jansak

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

DEC 4 1984

NOTE TO: Cardiac Pacemaker Registry Task Force Members

This is to let you know that we have completed the implementation strategy paper for presentation to Mr. Villforth and Mr. Benson, and to inform you that we plan to forward it to them by the end of this week. We want to share this with you in advance in lieu of a formal meeting to provide a preview of what we're finally proposing and to give you a chance to call to our attention any last minute concerns you might have. We felt this was particularly important since the thrust of the strategy has changed slightly as a result of recent discussions with HCFA staff, which led to a commitment by them to perform the data collection function via their intermediary network. This leaves to us the responsibility of housing the data under a registry and to perform some analysis of the data to identify generic device problems. Otherwise, the approach we're proposing basically reflects that which we've already discussed and agreed to.

Should you have any concerns or comments, please give either Donna Lenahan or me a call COB, Thursday (December 6). We'd like to express our thanks for all the help and advice you've offered, and we hope that the strategy document adequately reflects your work and input.

Donna M. Lenahan
Donna M. Lenahan

Robert C. Eccleston

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Memorandum

Date

From Co-Chairpersons, Pacemaker Registry Task Force

Subject Proposed Implementation Strategy for Pacemaker Registry Legislation -- INFORMATION/DECISION MEMORANDUM

To Director, CDRH
Deputy Director, CDRH

At the Center's "planning go-away" back in June, it was decided that OMS and Exec Sec staff should work together in reviewing the recently-passed pacemaker registry legislation and in developing an implementation strategy for your consideration. To carry out this charge, a task force was established with representatives from each of the Center's Offices and from GC and OLI. Over the last few months, the Task Force has dissected the law, has laid out the various tasks assigned by the statute, has deliberated how these tasks might be carried out, and has developed a number of implementation scenarios, along with cost and timing estimates. As you know, we have also begun a dialogue with various HCFA components in an effort to reach a mutual understanding of the law and what it entails, and to explore how our two agencies can collaborate effectively and avoid duplication of effort.

The attached report represents a summary of information drawn together by the task force and, relatively speaking, a consensus on the available options for carrying out the law as quickly and inexpensively as possible. The completion of this report, in a sense, marks the end of the Task Force's work. As you will note in the report, proposals are presented for "taking the next steps" and the means for entering the next implementation phase.

We would like to recognize the considerable effort that went into this report. We hope it adequately reflects the intensive thinking and researching of the Task Force that led to the development of this strategy paper.

Robert C. Eccleston   Donna M. Lenahan

Attachment

cc: Pacemaker Registry Task Force
CDRH Senior Staff
Ms. Suydam

Implementation
# of the
Cardiac Pacemaker Registry
# of the
Deficit Reduction Act of 1984

A Report by the

Cardiac Pacemaker Registry Task Force

EXECUTIVE SUMMARY/TABLE OF CONTENTS

Summary of Text — Page(s)

- What is the purpose of the paper? — 1

  The enclosed document, prepared by a Center-chaired task force, is intended to provide the history and events leading up to the passage of the cardiac pacemaker registry legislation, and to propose an "operational blueprint" for carrying out the law.

- What are the key elements of the law? — 1-3

  The "Deficit Reduction Act of 1984" (P.L. 98-369) was enacted on July 18, 1984. Section 2304 of the Act (which amends the Social Security Amendments) requires two major actions be taken by the Department in connection with Medicare reimbursement for pacemaker and pacer lead procedures. First, HCFA is to review its current post-implant monitoring guidelines to curb claims for too frequent or unnecessary monitoring. HCFA must also review present physician payment schedules, and hospital charges associated with pacemaker procedures are to be reviewed by the Prospective Payment Assessment Commission.

  Secondly, FDA is to establish a nationwide registry of all pacemakers and leads for which Medicare payment is made. Data such as the date and location of the procedure, type, model, and serial numbers of the devices, and warranty information are to be collected. The goal of this registry is threefold: (1) to assist the Secretary in making reimbursement decisions; (2) to track pacemaker performance; and (3) to determine when testing of allegedly malfunctioned pacemakers should be performed. The Act specifies that the registry and implementing regulations shall be in effect by January 1, 1985.

- What events led to the passage of the Act? — 4-6

  In 1982, the Senate Special Committee on Aging released a report, "Fraud, Waste, and Abuse in the Medicare Pacemaker Industry," which cited problems regarding pacemaker performance, cost, warranties, qualifications of implanting physicians, and pacemaker sales practices. In the report, the Committee proposed a number of actions for HHS/FDA, VA, SEC, and recommended legislation for a nationwide pacemaker registry. In July 1983, Senator Heinz and Congressman Wyden introduced virtually identical bills which provided the basis of the law now on the books.

- How does HCFA presently reimburse for pacemaker implants? 6

  In view of the cost-containment orientation of the law, the paper examines current HCFA reimbursement policies and procedures. Under the new Diagnostic Related Group/Prospect Payment System (DRG/PPS), pacemaker devices are no longer paid for separately; their costs are factored into the expenses of the entire treatment program, which are reviewed by Professional Review Organizations (PRO) for medical necessity, appropriateness, and quality of treatment. In this connection, HCFA is presently conducting 100% reviews of pacemaker implantations. The PRO's are also currently collecting warranty information on a limited basis. (Note that similar information is also gathered by intermediaries under contract with HCFA, e.g., Blue Cross/Blue Shield.)

- How can the registry data be used? 7-9

  As noted earlier, the registry data is to be used principally to give HCFA a "window" on pacemaker procedures, and as an adjunct to its reimbursement decision-making. It is expected that approximately 120,000 pacer implants/re-implants (along with lead implants) and 30,000 lead replacements will be reported to the registry each year. Each report will contain a minimum of 9 and perhaps as many as 20 data elements per report. Although the registry is not an adverse effects reporting system like DEN and MDR, it can serve as a useful tool in monitoring the long-term performance of pacemakers. The registry can also identify defective pacemakers still under warranty so that Medicare payments can be withheld.

- Are there other pacemaker registries after which FDA's registry could be modeled? 9

  A five-Center registry supported by FDA from 1974-1980 is still in operation, but is oriented somewhat differently in terms of the type of data collected. In 1982, ECRI established a National Implant Registry which, on a subscription basis, maintains an informational file on pacemaker patients, pacemaker recalls, corrective actions, etc. for hospitals. Also in 1980, the VA initiated a Pacemaker Surveillance System to provide transtelephonic monitoring of patients and cardiology consultation to referring the VA medical centers. In reviewing the focus and scope of these registries, it appears that none are suitable in their present form to meet the requirements of the law. It should be noted that as many as five private sector organizations (including the first two noted above) have written the Center indicating an interest in assisting FDA in maintaining the registry.

- What are the implementation options? 9-11

Initially, the Task Force conceived of three possible options for establishing and maintaining the registry. These were based on the premise that the registry would serve as the vehicle for data collection and analysis. They were: (1) an in-house effort; (2) an extramural contract; and (3) use of HCFA's PRO system to collect the data, with FDA to provide long-term performance trend analyses. The Task Force felt that having HCFA operate the registry was the option of choice because it would remove FDA from the middle of the reporting chain, and, since HCFA now collects much of the information required by law, would avoid re-inventing the wheel.

Recent discussions with HCFA staff have led to a preliminary agreement that HCFA assume lead responsibility for collecting the data, and that FDA will maintain and analyze the data base. The idea of using the PRO system has been discarded, in favor of data collection by the approximately 60 intermediaries which handle the agency's claims processing. The data would be maintained as part of HCFA's permanent records and transmitted periodically to FDA for analysis.

FDA would then use the data to identify and analyze generic performance problems with pacemakers and leads. The options for setting up and running the registry are basically the same as the first and second options above. The chief advantages of the contract route -- which the Task Force favors -- are that it would avert a drain on in-house resources (although some in-house scientific review would still be needed), and it would be in keeping with OMB's A-76 Directive, which urges greater use of Federal service contracts.

- Is a special committee needed to advise and oversee the Center in establishing the registry? 11

The Task Force believes so. Such a group should be charged with the overall coordination of registry activities. Since the present composition of the Task Force does not include HCFA representatives, it is felt that a new "coordinating committee" should be formed, with HCFA representation. Public input into the development of the registry and the underlying regulations can be obtained through the administrative rule-making process, through discussions with constituencies represented on the Center's Cardiovascular Devices Panel, and through informal contacts with appropriate outside organizations.

- What about funding? 11-13

Although no appropriation accompanied the legislation, the Senate Appropriations Committee recommended that FDA file a supplemental request to its FY 85 budget. Departmental efforts to secure additional funding have been made on two tracks. The first is a supplemental request for $1.2 million to be added to the FY 85 budget. The second is the inclusion of a line item in FY 86 budget for 11 FTE's and $1.2 million. Irrespective of the implementation option chosen, a formal agreement with HCFA is advisable. There is some thinking that the data collected could be sold to hospitals, cardiology organizations, etc., to help defray some of the registry implementation costs.

- How much time is involved in getting the registry up-and-running? 13-15

One of the first steps is to negotiate an interagency agreement or memorandum of understanding with HCFA in order to clearly define each agency's responsibilities. Three to six months is estimated as the time needed to complete negotiations and obtain all the necessary clearances. Although the Task Force recognizes and is concerned about the time needed to consummate an agreement, we support the idea of a formal working agreement. HCFA has suggested keeping the working arrangements on an informal basis.

Insofar as regulations development is concerned, it is unclear whether FDA alone, HCFA alone, or an interagency effort is required to issue implementing regulations. The Center's FY 85 regulations plan includes having a proposed rule out of CDRH in June and out of FDA by September of next year.

Regarding establishment of the actual registry, if we elect to go the contract route, it is expected that final awarding of a contract would require 4-6 months.

- Will there be any impact of the registry requirements on existing regulations? 15-16

There are three potential areas of the Center's device program that must be taken into account as the registry regulations are developed. First, current GMP regulations require investigations and records of complaints, which could include explanted pacemakers. Since the registry legislation calls for providers to return explanted pacers to manufacturers, some attention must be given to this issue. The second area is MDR. Failures of pacemakers, especially in "pacemaker dependent" patients, might meet the reporting criteria contained in the MDR rule. Again, the registry regulations must be developed so as to not overlap or conflict with current MDR requirements. Finally, the registry regulations should specifically address pertinent FOIA issues given the confidential nature of the data.

- What are Congress' expectations regarding the registry? 16

  From conversations with staff from the Senate Committee on Aging, it is clear that Senator Heinz will keep a watchful eye on FDA's progress in carrying out this law. Although there is general agreement between FDA and the Committee that the January 1, 1985 deadline is unrealistic, the Committee has not foreclosed the possibility of oversight hearings early in 1985. In view of this, the Task Force favors the idea of sending a letter report to Senator Heinz and other appropriate Congressmen that describes our implementation plans. It should also be noted that the existence of this legislation and the recent hearings on the Medtronic pacemaker lead situation has spawned even wider Congressional interest in the subject of Medicare reimbursement for defective products, particularly pacemakers.

- What does the implementation "blueprint" look like? 16-17

  The Task Force believes that implementation can be viewed in a phased approach. Phase I, for example, would include actions such as establishing a Coordinating Committee, soliciting input from HCFA and outside groups, and initiating interagency negotiations with HCFA. Phase II would include early work to develop the implementing regulations, initiating the contract process (if necessary), and preparing an implementation report for transmittal to the Congress. Phase III calls for publication of the proposed regulation. Phase IV includes promulgation of the final regulations and, if necessary, the development of educational initiatives to inform the medical community and the pacemaker industry about the specific requirements contained in the regulations. The Task Force anticipates that Phase I could be accomplished during the first quarter of FY 85; Phase II during the second quarter; Phase III during the fourth quarter; and Phase IV during the third quarter of FY 86.

- Is their general consensus within the Center on this strategy? 17-19

  This implementation paper has been shared with Center senior staff for review and comment. It appears that there is general unanimity on the approach to this new initiative.

- What are the Task Force's recommendations? 19-20

  Eight separate proposals have been made by the Task Force, all of which are designed to take the Center and HCFA into the next implementation phase, i.e., to solidify a working arrangement between both agencies, and to "iron out" the mechanics of collecting the required data, "feeding" it to the registry, and providing some performance trend analysis. Based on your decisions, OMS will take the lead "coordinator" role in proceeding to the next phase of implementation.

Attachment A.

CARDIAC PACEMAKER REGISTRY TASK FORCE

Robert C. Eccleston, Co-Chairperson
Office of the Center Director, CDRH

Bonnie H. Malkin
Office of the Center Director, CDRH

Donna M. Lenahan, Co-Chairperson
Office of Management and Systems, CDRH

Glenn A. Rahmoeller
Office of Device Evaluation, CDRH

William F. Hooten
Office of Compliance, CDRH

Walter L. Scott, Ph.D.
Offitce of Training and Assistance, CDRH

Leslie S. Weinstein
Office of Standards and Regulations, CDRH

Wendy S. Johnson
Office of Science and Technology, CDRH

Robert A. Skufca, D.O.
Office of Health Affairs, CDRH

Janet G. Hardy
Office of Legislation and Information, FDA

Kathy Schroeher
Office of General Counsel, FDA Division

Attachment B.

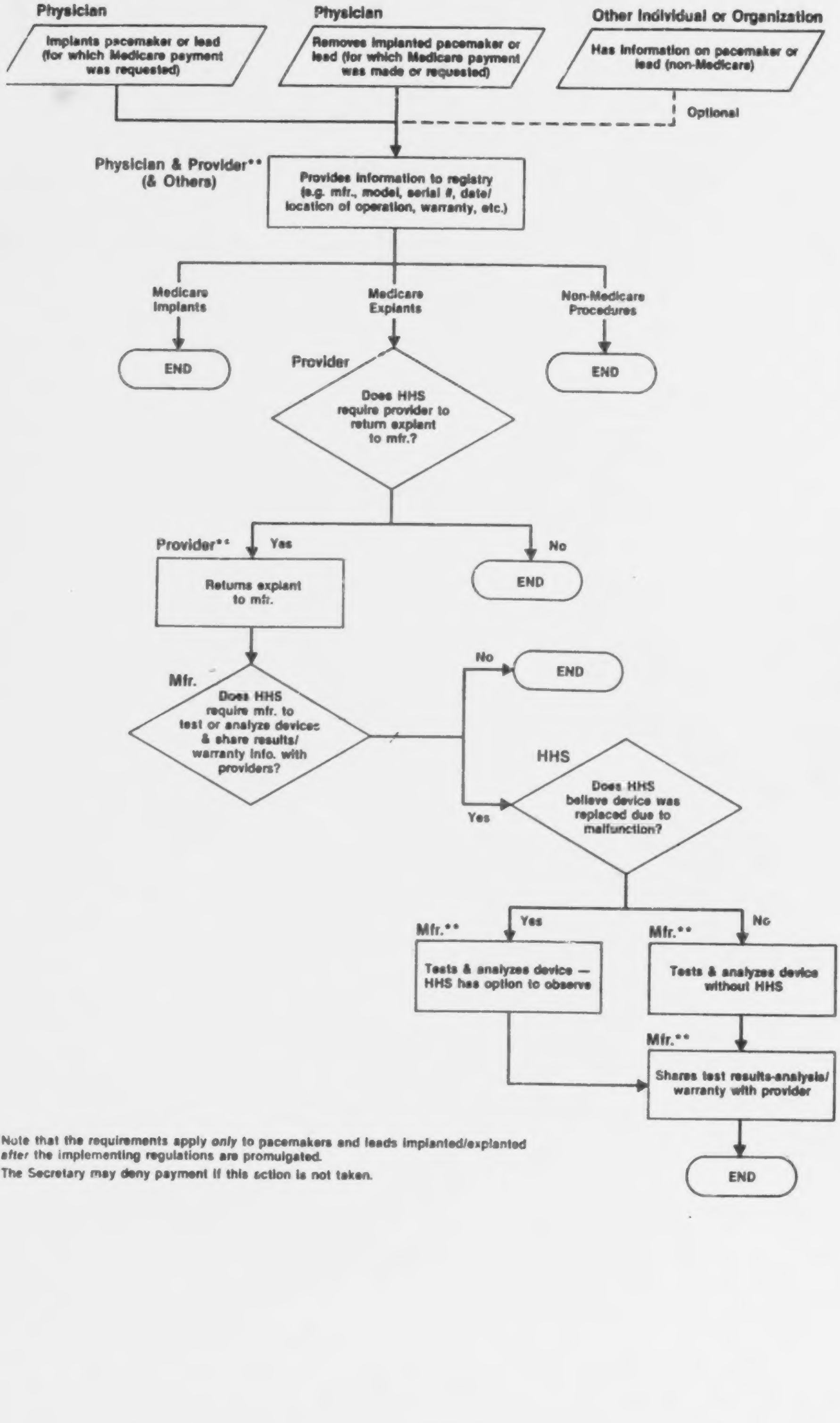
[Please see June 23, 1984 Appendix item, above, for Pacemaker provisions of Deficit Reduction Act of 1984.]

Attachment C.

[Please see June 23, 1984 Appendix item, above, for Pacemaker provisions of Deficit Reduction Act of 1984.]

Attachment D.

Flow Chart of Pacemaker Registry Legislation Requirements*


Physician
Implants pacemaker or lead (for which Medicare payment was requested)
Physician
Removes implanted pacemaker or lead (for which Medicare payment was made or requested)
Other Individual or Organization
Has information on pacemaker or lead (non-Medicare)
Optional
Physician & Provider** (& Others)
Provides information to registry (e.g. mfr., model, serial #, date/location of operation, warranty, etc.)
Medicare Implants
END
Medicare Explants
Non-Medicare Procedures
END
Provider
Does HHS require provider to return explant to mfr.?
Provider**
Yes
No
Returns explant to mfr.
END
Mfr.
Does HHS require mfr. to test or analyze devices & share results/warranty info. with providers?
No
END
Yes
HHS
Does HHS believe device was replaced due to malfunction?
Yes
No
Mfr.**
Tests & analyzes device — HHS has option to observe
Mfr.**
Tests & analyzes device without HHS
Mfr.**
Shares test results-analysis/warranty with provider
END

*Note that the requirements apply *only* to pacemakers and leads implanted/explanted after the implementing regulations are promulgated.

**The Secretary may deny payment if this action is not taken.

Attachment E.

[The following dated items, appearing separately elsewhere in the Appendix, were attached at Tab E.]

August 14, 1984 Letter from Robert C. Eccleston, FDA, to Stanley H. Katz, HCFA;

Memorandum of August 29, 1984 meeting between FDA and HCFA re: "Implementation of the Pacemaker Registry";

September 9, 1984 Letter from Robert C. Eccleston, FDA, to Stanley Katz, HCFA;

September 26, 1984 Letter from Stanley Katz, HCFA, to Robert C. Eccleston, FDA.

Attachment F.

FDA Pilot Registry:

FDA's pilot registry (1974-1980) was implemented to gather safety and performance data on a variety of pacemaker makes and models. Five pacemaker centers followed over 8,000 pacemakers. Leads were not registered until the last two years of the registry. The registry collected detailed medical history and patient followup data (until the death of the patient or explant of the pacemaker), in addition to the type of data that will be required in the new registry. Although the primary purposes of the two registries are different, the experience of the earlier registry will be valuable in establishing the new registry. The pilot registry was maintained for six years at a total cost of over one million dollars.

The individual physicians who participated in FDA's earlier registry have continued to collect data. This data is periodically published in PACE, the journal of the North American Society for Pacing and Electrophysiology (NASPE). One of these physicians has expressed an interest in participating in the development of the registry.

The National Implant Registry:

ECRI (formerly the Emergency Care Research Institute) is a non-profit organization devoted to improving patient care through scientific, technical, and educational programs related to the delivery of health services.

Its primary task is the assessment of health care technology. ECRI represents the user, the hospital, the health care professional, and the patient, i.e., those who ultimately pay the cost of medical devices and the penalties for their deficiencies.

ECRI operates the National Implant Registry (NIR). The NIR, which was established in 1982, is a service offered to health care providers (primarily hospitals) that:

- maintains central, computerized records of patients, implants, hospitals, and physicians;
- matches records against recall notices and product warnings;
- alerts hospitals and physicians to defects and deficiencies;
- traces patients to facilitate future contact and corrective action if an implant proves defective; and
- provides consultation services.

The cost for the service ranges from $16.50 to $24.40 per implant, depending on the number of implants per institution. An active subscription effort has only recently begun. At present, fewer than one percent of hospitals subscribe to NIR. The president of ECRI has expressed an interest in participating in the development and maintenance of this registry.

The Veterans Administration Pacemaker Surveillance System:

In 1981-82 the Veterans Administration (VA) established a nationwide Pacemaker Surveillance Program. The purpose of the program is to provide transtelephonic monitoring of pacemaker patients and cardiology consultation to referring (VA) medical centers in a timely manner. The Pacemaker Center's services include:

- transtelephonic monitoring of patients;
- alerts to referring physicians of patient condition and problems;
- 24-hour coverage for pacemaker emergencies;
- scheduling of routine transtelephonic checks for each patient; and
- maintenance of a computerized data base for analyses and furnishing of certain reports to referring medical centers.

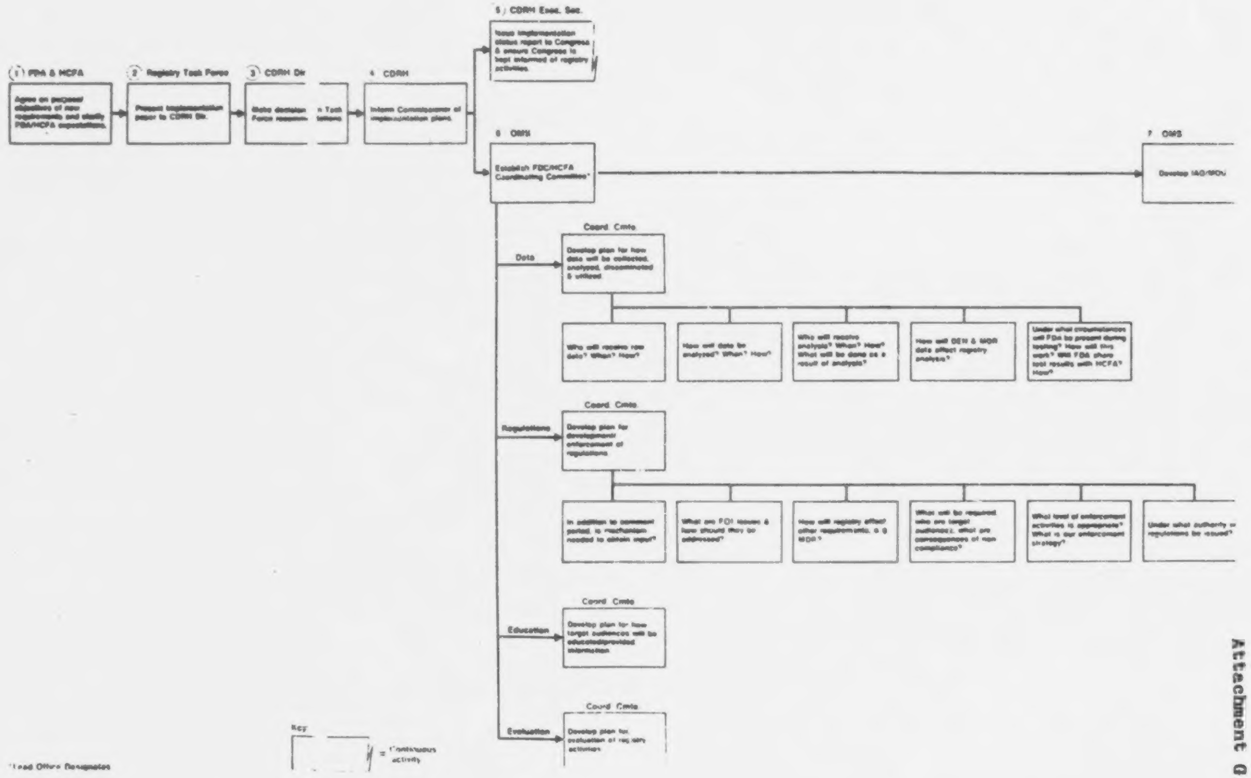
The Pacemaker Center also tests explanted pacemakers to confirm suspected failures.

The Pacemaker Surveillance System currently registers 10-15,000 patients throughout the country, most of whom received their pacemakers at VA hospitals. The data management and computer operations aspect of the system are managed by the individual pacemaker centers. Start-up costs for the East Coast Center were $250-300K. Annual maintenance requires approximately 4-6 staff people and $70-80,000 (excluding salaries).

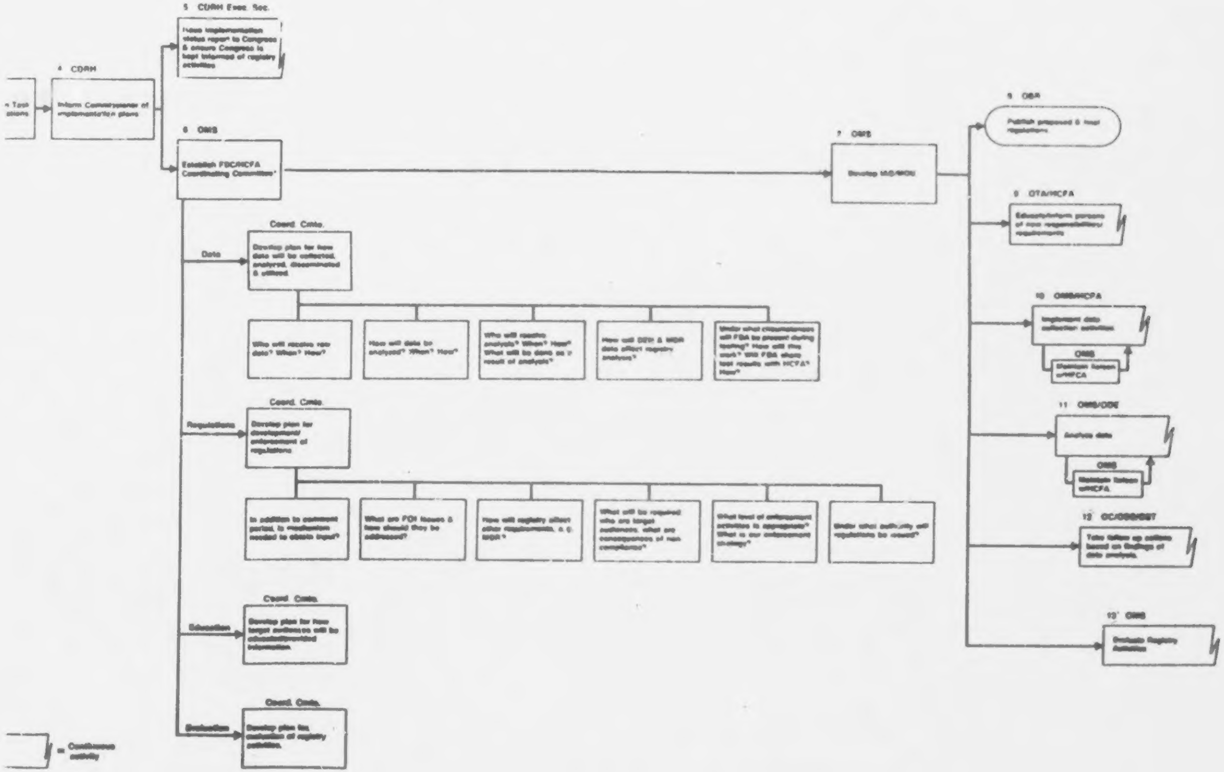
The Director of the Pacemaker Center has offered his cooperation in establishing this registry, and the computer software which the VA has developed.

Attachment G.

Basic Implementation Strategy for Cardiac Pacemaker Registry


1 FDA & HCFA
Agree on purpose/ objectives of new requirements and clarify FDA/HCFA expectations.
2 Registry Task Force
Present implementation paper to CDRH Dir.
3 CDRH Dir
Make decision … n Task Force recommen… tions
4 CDRH
Inform Commissioner of implementation plans.
5 CDRH Exec. Sec.
Issue implementation status report to Congress & ensure Congress is kept informed of registry activities.
6 OMS
Establish FDA/HCFA Coordinating Committee*
7 OMS
Develop IAG/MOU
Data
Coord Cmte
Develop plan for how data will be collected, analyzed, disseminated & utilized
Who will receive raw data? When? How?
How will data be analyzed? When? How?
Who will receive analysis? When? How? What will be done as a result of analysis?
How will DEN & MDR data affect registry analysis?
Under what circumstances will FDA be present during testing? How will this work? Will FDA share test results with HCFA? How?
Regulations
Coord Cmte
Develop plan for development/ enforcement of regulations
In addition to comment period, is mechanism needed to obtain input?
What are FOI issues & how should they be addressed?
How will registry affect other requirements, e.g. MDR?
What will be required who are target audiences, what are consequences of non compliance?
What level of enforcement activities is appropriate? What is our enforcement strategy?
Under what authority
regulations be issued?
Education
Coord Cmte
Develop plan for how target audiences will be educated/provided information
Evaluation
Coord Cmte
Develop plan for evaluation of registry activities
Key
= Continuous activity
*Lead Office Designation

Basic Implementation Strategy for Cardiac Pacemaker Registry


4 CDRH
Inform Commissioner of implementation plans
5 CDRH Exec. Sec.
Issue implementation status report to Congress & ensure Congress is kept informed of registry activities
6 OMS
Establish FDA/HCFA Coordinating Committee
Data
Coord. Cmte.
Develop plan for how data will be collected, analyzed, disseminated & utilized
Who will receive raw data? When? How?
How will data be analyzed? When? How?
Who will receive analysis? When? How? What will be done as a result of analysis?
How will DEN & MDR data affect registry analyses?
Under what circumstances will FDA be present during testing? How will the work? Will FDA share test results with HCFA? How?
Regulations
Coord. Cmte.
Develop plan for development/enforcement of regulations
In addition to comment period, is mechanism needed to obtain input?
What are FOI issues & how should they be addressed?
How will registry affect other requirements, e.g. MDR?
What will be required who are target audiences, what are consequences of non-compliance?
What level of enforcement activities is appropriate? What is our enforcement strategy?
Under what authority will regulations be issued?
Education
Coord. Cmte.
Develop plan for how target audiences will be educated/provided information.
Evaluation
Coord. Cmte.
Develop plan for evaluation of registry activities.
7 OMS
Develop MAO/MOU
8 OBR
Publish proposed & final regulations
9 OTA/HCFA
Educate/inform persons of new responsibilities/requirements
10 OMS/HCFA
Implement data collection activities
OMS
Maintain liaison w/HCFA
11 OMS/ODE
Analyze data
OMS
Maintain liaison w/HCFA
12 OC/ODE/OST
Take follow-up actions based on findings of data analysis.
13 OMS
Evaluate Registry Activities
= Continuous activity

Attachment H.

BIOMETRIC RESEARCH INSTITUTE INC
1401 Wilson Boulevard • Suite 400 • Arlington, VA 22209 • (703) 276-0400

August 7, 1984

Mr. John C. Villforth
Director
Center for Devices & Radiological
Health
5600 Fishers Lane
Room 502
Twinbrook Bldg.
HFZ-1
Rockville, Maryland 20857

Dear Mr. Villforth:

Biometric Research Institute is very much interested in helping the Center for Devices and Radiological Health implement the pacemaker registry required by the Deficit Reduction Act of 1984.

As you may know, BRI worked closely with the Center and the Intraocular Lens Manufacturers Association to develop and implement the Adjunct Safety Study for intraocular lenses. As part of this study, BRI processed registry information and preoperative, operative and up to 18-month postoperative results on nearly 500,000 implant patients. At the peak of the study, we were adding data on approximately 15,000 new surgery patients to the computer files each month.

This, along with our general experience in regulatory data processing and our knowledge of the Agency's requirements for studies on medical devices, makes BRI particularly well suited to work on the pacemaker registry.

Please send us a copy of the request for proposals to implement the pacemaker registry when the RFP becomes available.

Thank you for your assistance.

Yours truly,

Frank L. Hurley, Ph.D.
Executive Vice President

FLH:jah

BAYLOR UNIVERSITY MEDICAL CENTER
Boone Powell, Jr., F.A.C.H.A.
President

H. L. & Ruth Ray Hunt Heart Center
John W. Hyland, M.D.
Director

Associates
John W. Hyland, M.D.
James L. Mason, M.D.
Richard M. Sohr, M.D.
Michael S. Donsky, M.D.
Walter L. Berman, M.D.
Charles M. Gottlich, M.D.
James H. Shelton, M.D.

July 25, 1984

John C. Villforth HFZ-1
Director
Center for Devices and Radiological Health
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Mr. Villforth:

It is my understanding that the Food and Drug Administration will, in the near future, organize and implement a federal registry for cardiac pacemaker patients. I wish to submit a request to be included on the mailing list for any of the following FDA notifications:

1. Any Request for Proposals related to the development, implementation, or operation of such a registry.
2. Any new regulations resulting from the creation of such a registry.
3. Any requests for public comment on the creation of the registry or related regulations.

Our Pacemaker Department has a very comprehensive Pacemaker Patient Management System that will need to be interfaced to your federal registry. As much advance notice, as possible, of the above information will help us to fully meet your new requirements.

We recognize the need for such a registry and would like to cooperate in any way we can.

Please submit correspondence to the following address:

Edward L. Bond, Ph.D.
Heart Center
Baylor University Medical Center
3600 Gaston Avenue
Dallas, TX 75246

Sincerely,

Edward L. Bond

Edward L. Bond, Ph.D.
Director, Computer Science

3500 Gaston Avenue • Dallas, Texas 75246 • (214) 820-3333 • Texas Toll Free 800-442-2212 • Cable Address BAYLORDAL

PACEMAKER CENTER

UNIVERSITY OF SOUTHERN CALIFORNIA SCHOOL OF MEDICINE

PARKVIEW MEDICAL BUILDING • 1420 SAN PABLO ST • LOS ANGELES CA 90033 • (213) 225-1555

July 11, 1984

Mr. John Villforth
Director of Center for
Devices and Radiological Health
5600 Fishers Lane
Rockville, Maryland 20857

Dear Mr. Villforth:

As you know my colleagues, Drs. Victor Parsonnet, Seymour Furman, Robert Hauser, Bernard Goldman, and I have been vitally interested in the performance levels of permanent cardiac pacemakers, including pulse generators and leads. We have had a ten year of commitment to the collection of data from our centers as a collaborative effort. We are, of course, watching with considerable interest the move by the Federal Government towards a central registration system, for a large aliquot of pulse generators and leads, which will be under the aegis of the Food and Drug Administration.

Because of our particular interests and background, we would appreciate the opportunity to establish a dialogue between ourselves and the Food and Drug Administration as to the future direction of any governmental or governmental sponsored national cardiac pacemaker registration system. We are particularly concerned about the maintenance of a high quality patient and physician-need oriented thrust to such a registry. Because of our unique experience in the collection of high quality concentrated data, we would be especially interested in exploring the possibility of the development of a detailed, unique, multicentric, concentrated data base for the assessment, on an ongoing basis, of not only hardware performance but the clinical basis and expectation of cardiac pacing in general.

I would be very pleased to discuss these questions with you at your convenience.

Looking forward to hearing from you in the near future, I remain,

Respectfully,

Michael Bilitch, M.D.
Associate Professor of Medicine

MB:kh

cc: Dr. Hauser
Dr. Furman
Dr. Parsonnet
Dr. Goldman
Dr. Harthorne
Dr. Waldo

ED MEDICAL
ORATION

PES PACEMAKER EVALUATION SERVICE
CORPORATION
A UNITED MEDICAL COMPANY

86 HADDON AVENUE
P.O. BOX 117
HADDONFIELD, NEW JERSEY 08033
(609) 354-2255

October 30, 1984

Mr. John Villforth
Director
Center for Devices and Radiological Health
FDA HFZ-1
5600 Fishers Lane
Rockville, MD 20857

Dear Mr. Villforth:

United Medical Corporation is the leader in cardiac-related services for hospitals, physicians and the exacting pharmaceutical industry. We have earned an excellent reputation for pacemaker follow-up, Holter monitoring, and for our unique facilities for computer-management of the plethora of information drug companies must submit to your organization.

The Deficit Reduction Act of 1984, recently signed by the President, directs the Food and Drug Administration and the Department of Health and Human Services to institute a pacemaker registry of all devices and leads reimbursed under Medicare. United Medical hereby seeks your invitation to make a proposal to design and manage the pacemaker registry.

We have monitored the performance of virtually all pacemakers and leads now in use during our 13 years of experience in this technical field. In short, we can offer the objectivity of a consultant, and the expertise of professionals. Moreover, we immediately have the data processing capability, and in-house experts to program the government's information.

Under our direction, the pacemaker and lead registry can be up and running in 90 days.

We can offer such swift assurances because we frequently have dealt with drug company studies, for example, involving vast quantities of data. We have developed a logical retrieval system which is essential for extracting information, whether it is used for tracking pacemaker performance, or for planning purposes. United Medical can offer assistance in the many uses of the information. We can install a computer terminal at the FDA in order that you may readily monitor the registry.

As I understand your requirements at this stage, I encourage you to consider United Medical. I will telephone you shortly to discuss your requirements in more detail.

Sincerely,

J.J. Johnson

J.J. Johnson
President

JJJ/cjd
cc: David Applebaum
Research Assistant
Congressman James J. Florio
1st District New Jersey
One Colby Avenue #16-17
Stratford, NJ 08084

DEPARTMENT OF HEALTH AND HUMAN SERVICES

AUG 14 1984

Frank L. Hurley, Ph.D.
Executive Vice President
Biometrics Research Institute, Inc.
1401 Wilson Boulevard, Suite 400
Arlington, Virginia 22209

Dear Dr. Hurley:

Thank you for your letter of August 7, 1984 concerning the Food and Drug Administration's new responsibility in establishing a national registry for cardiac pacemaker and leads as called for in the "Deficit Reduction Act of 1984" (P.L. 98-369), which was enacted last month. I appreciate your calling to our attention the experience you have gained in operating the intraocular lens registry and in regulatory data processing in general.

With the final language now decided upon, we have begun to analyze the bill's specific requirements and how we might implement them. We view the main goal of this legislation to be to reduce unnecessary Medicare expenditures through a quality control system of recording implantation and warranty information, and through testing pacers and leads reported to have malfunctioned. Thus we will need to consult and work closely with the Health Care Financing Administration (HCFA) in terms of data and cost sharing and general implementation measures.

Should FDA decide to contract for certain data collection and analysis in support of the registry, we will probably issue a request for extramural proposals. We will, of course, keep your name on file and will be pleased to notify you of our intended actions.

Sincerely yours,

/s/ John C. Villforth

John C. Villforth
Director
Center for Devices and
Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NOV 7 1984

Mr. J.J. Johnson
President, Pacemaker Evaluation Service
United Medical Corporation
89 Haddon Avenue
P.O. Box 117
Haddonfield, New Jersey 08033

Dear Mr. Johnson:

Thank you for your letter of October 30, 1984 concerning the Food and Drug Administration's new responsibility in establishing a national registry for cardiac pacemakers and leads as called for in the legislation the Congress passed earlier this year and signed by the President on July 18. I appreciate your calling to our attention the experience your company has had in the field of cardiac pacemakers and pacer leads.

With the legislation now in place, we have begun to analyze the specific requirements of the law and how we might implement them. We view the main goal of this legislation to be to reduce unnecessary Medicare expenditures through a quality control system of recording implantation and warranty information, and through testing pacers and leads that have reportedly malfunctioned. Thus we have begun to consult with the Health Care Financing Administration (HCFA) in terms of data and cost-sharing and general implementation measures.

Should FDA decide to contract for certain data collection and analysis in support of the registry, we will likely issue a request for extramural proposals. We will, of course, keep your name on file and will be pleased to notify you of our intended actions. I would ask that, in the interim, should you have any comments or questions, you contact either Mr. Robert Eccleston of my office (301-443-6220), or Mrs. Donna Lenahan of our Office of Management and Systems (301-443-5807).

Sincerely yours,

/s/ John C. Villforth

John C. Villforth
Director
Center for Devices and
Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

AUG 7 1984

Edward L. Bond, Ph.D.
Director, Computer Science
Heart Center
Baylor University Medical Center
3600 Gaston Avenue
Dallas, Texas 75246

Dear Dr. Bond:

Thank you for your letter of July 25, 1984 concerning the Food and Drug Administration's new responsibility in establishing a national registry for cardiac pacemakers and leads as called for in legislation that the Congress has passed and on July 18 the President approved. I appreciate your calling to our attention the experience you and the Center's Pacemaker Department have gained in operating the Pacemaker Patient Management System.

As I mentioned above we understand that the "Deficit Reduction Act of 1984" (which contains the pacemaker registry requirement) was signed into law two weeks ago (P.L. 98-369). With the final language now decided upon, we have begun to analyze the bill's specific requirements and how we might implement them. We view the main goal of this legislation to be to reduce unnecessary Medicare expenditures through a quality control system of recording implantation and warranty information and testing pacers and leads reported to have malfunctioned. Thus we will need to consult and work closely with the Health Care Financing Administration (HCFA) in terms of data and cost-sharing and general implementation measures.

Should FDA decide to contract for certain data collection and analysis in support of the registry, we will probably issue a request for extramural proposals. We will, of course keep your name on file and will be pleased to notify you of our intended actions.

Sincerely yours,

/s/ John C. Villforth

John C. Villforth
Director
Center for Devices and
Radiological Health

JUL 26 1984

Michael Bilitch, M.D.
Associate Professor of Medicine
University of Southern California School of Medicine
Parkview Medical Center
1420 San Pablo Street
Los Angeles, California 90033

Dear Dr. Bilitch:

In John Villforth's absence, I am responding to your letter of July 11, 1984, concerning legislation that the Congress has passed and on July 18 the President approved requiring FDA to establish a national registry for cardiac pacemakers and leads. I appreciate your calling to our attention your experience, and that of your colleagues, in the collection of data on pacemakers.

As I mentioned above, we understand that the "Deficit Reduction Act of 1984" (which contains the pacemaker registry requirement) was signed into law this past week (P.L. 98-369). With the final language now decided upon, we have begun to analyze the bill's specific requirements and how we might implement them. We view the main goal of this legislation to be to reduce unnecessary Medicare expenditures through a quality control system of recording implantation and warranty information and testing pacers and leads reported to have malfunctioned. Thus we will need to consult and work closely with the Health Care Financing Administration (HCFA) in terms of data and cost sharing and general implementation measures.

Should FDA decide to contract for certain data collection and analysis in support of the registry, we will probably issue a request for extramural proposals. At that time, we would welcome a proposal from you.

Sincerely yours,

/s/ James S. Benson

James S. Benson
Deputy Director
Center for Devices and
Radiological Health

cc: Mr. Villforth
Mr. Goldstein/Ms. Suydam
Cardiac Pacemaker Registry
Task Force

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
Rockville MD 20857

JUL 5 1984

Joel J. Nobel, M.D.
President
Ms. Susan Lalli-Ascosi
Director for Hospital Services
National Implant Registry
5200 Butler Pike
Plymouth Meeting, Pennsylvania 15462

Dear Dr. Nobel and Ms. Lalli-Ascosi:

This is in response to your letters of June 22 to me and Dr. Koop concerning the pending Congressional legislation that will, when enacted, require FDA to establish a national registry for cardiac pacemakers and leads. I appreciate your calling to my attention the services of the National Implant Registry.

I should note that since your letter, the bill has moved closer to final passage, with House and Senate conferees agreeing to a final proposal comprised of language from both versions. I understand that the full House and Senate approved the legislation on June 27, and that the main thrust of the bill has not changed from the earlier proposals.

Given that the main premise of this legislation is to curb unnecessary Medicare expenditures through a quality control system of recording the implantation and warranty dates and testing pacers and leads reported to have malfunctioned, we will need to consult with the Health Care Financing Administration (HCFA) about data and cost sharing. We are, at present, awaiting the final wording and passage of the bill before deciding on implementation procedures. If FDA decides to contract for certain data collection and analysis in support of the registry, we will probably issue a request for extramural proposals. At that time, we would welcome your proposal.

Sincerely yours,

John C. Villforth
Director
Center for Devices and
Radiological Health

Attachment I.

United States Senate
COMMITTEE ON APPROPRIATIONS
WASHINGTON, D.C. 20510

HHS-OS-EXEC
Sep 4 10 42 AM '84

August 29, 1984

The Honorable Margaret Heckler
Secretary
Department of Health and Human Services
Washington, D. C.

Dear Margaret:

The recent investigation by the Food and Drug Administration into reports of defective cardiac pacemakers raise serious questions regarding the financial implications for the Medicare trust fund if it is expected to absorb the cost of replacement operations. One House Member has estimated the cost to the trust fund could reach tens of millions of dollars.

Should Medicare foot the bill for replacement operations in cases where there is a manufacturer defect? As a matter of public policy, the answer must be a resounding no.

I fully realize that you have not yet reached a final decision regarding the specific case under investigation and I do not mean to pre-judge the outcome since I do not have available to me the evidence that has been uncovered by the Food and Drug Administration. But this case demonstrates that the Department, and perhaps the Congress, needs to address the issue of how aggressively we intend to hold manufacturers liable for defects in their medical products, how strict that standard should be and whether the Department requires additional legislative authority in order to act aggressively in these cases once a determination of the factual situation has been reached.

In my view the Department has sufficient legal authority under Section 518(b) to move promptly to require manufacturers to reimburse the government for any expenses to Medicare for replacement operations. This authority was added as part of the Medical Devices Act and, as you know, the Congress has been very critical of the Department's implementation of that legislation.

Therefore, I would appreciate your responses to the following questions:

> What is the total estimated cost to Medicare in the current fiscal year for pacemaker installation operations? How much of that cost is attributable to replacement operations for defective pacemakers?

(2) Do you believe that the Department has sufficient legal authority under Section 518(b) of the Federal Food, Drug and Cosmetic Act to require manufacturers (of defective pacemakers in this case) to assume the cost of replacement operations?

(3) When can the Congress expect a determination whether Section 518(b) will be invoked in the case now under consideration by the Food and Drug Administration?

(4) Regardless of the decision in this specific case, does the legal standard set forth in Section 518(b) place too high a burden of proof on the Department before it can act? Should the Congress adopt a stricter standard of liability for manufacturers in cases such as this?

While most of the foot-dragging by Health and Human Services in implementing the Medical Devices Act of 1976 preceded your taking the helm at the Department, I urge you to seize the initiative in seeing that a determination in this case is expeditiously reached and, more importantly, in seeing that the Department address the broader question of liability by medical device manufacturers in light of the Medicare trust fund's precarious financial position.

I look forward to hear from you.

Sincerely,

William Proxmire, U. S. S.
Ranking Minority Member
Subcommittee of Labor-HHS-Education

[illegible]

U.S. House of Representatives
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
Washington, D.C. 20515

May 8, 1984

The Honorable Margaret M. Heckler
Secretary
Department of Health and Human Services
200 Independence Avenue, S. W.
Washington, D. C. 20201

Dear Madame Secretary:

The Subcommittee on Oversight and Investigations has a long-standing interest in the activities of the Food and Drug Administration (FDA) in implementing the provisions of the 1976 Medical Device Amendments to the Food, Drug, and Cosmetic Act. Most recently, on March 13, 1984, the Subcommittee conducted a hearing regarding FDA's role in responding to reported incidents of pacemaker lead failures.

While this hearing dealt primarily with the role of FDA, another issue was raised of particular importance to the Subcommittee and we expect to your Department. That issue involves the reimbursement policies and the practices of Medicare and other Federal health insurance programs to reimburse the medical expenses incurred in the replacement of these failed pacemaker leads.

The policy of the pacemaker manufacturer involved in this case, Medtronic, Inc., was that they would reimburse the patients for otherwise unreimbursed medical expenses for the benefit of the patient up to $600. It is our understanding, however, that 85% to 90% of pacemaker patients are covered by Medicare which would initially provide reimbursement for the expenses of extracting and reimplanting the pacemaker leads. This is a procedure which could cost as much as $5,000 per replacement and, in total, represent millions of taxpayer dollars.

The Subcommittee is particularly concerned about this situation where it appears that the Federal government would be insuring against the irresponsibility or the negligence of the pacemaker manufacturer.

The Honorable Margaret M. Heckler
May 8, 1984
Page 2

The Subcommittee would appreciate a full report from the Department on your policies and practices in paying for the replacement of failed pacemakers or related pacemaker devices and a description of any efforts that are made by the Department to seek reimbursement from the manufacturer if it is determined that a failure was a result of negligence or fault of that manufacturer.

The Subcommittee will appreciate your prompt response to this request.

John D. Dingell
Chairman
Subcommittee on
Oversight and Investigations

JDD:PKsz

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

AUG 30 1984

SEP 5 1984

The Honorable John D. Dingell
Chairman
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

This is in response to your letter regarding the Medicare policy regarding payment for medical and hospital services associated with recalled medical devices or those under warranty, especially pacemakers and pacemaker leads.

Medicare has reimbursed hospitals and physicians for those services not reimbursed by manufacturers. Under the provisions of the original Medicare law, Medicare was the primary payer regardless of any other insurance involved, and such payments were not subject to recovery. However, section 1862(b) of the law has been amended to condition Medicare payments on recovery by the program if third party payment is made under liability insurance.

Under Medicare regulations, the program may take legal action against responsible parties and liability insurers to recover Medicare payments if no liability claim is filed by the beneficiary or may recover from any liability insurance payment made to the beneficiary. We believe this provision to be applicable in cases involving defective devices if the patient has a claim against the product's manufacturer based on the defect, and the claim is covered by the manufacturer's liability insurance. Success in effecting recovery under this provision is, of course, dependent on establishing the manufacturer's liability, which may be complicated by varying State laws on liability. To the extent that manufacturers comply with the terms of their warranties for replacement of devices, Medicare-covered expenses are not incurred. However, where a manufacturer agrees to pay only a fixed amount for uninsured medical and hospital expenses incurred to replace such a device, the Medicare program has no recourse under current law except to make a conditional payment and pursue recovery under the liability insurance provisions. Accordingly, we are instructing our contractors to make conditional payments in the cases involving defective pacemaker leads. At the same time, we are pursuing recovery from the manufacturer or its liability insuror.

Sincerely,

Margaret M. Heckler

Margaret M. Heckler
Secretary

cc: FD
ANN

Smart = nimble team
use demo style

DEC 12 1984

TO : John Berry cc'd

SUBJECT : Pacemaker Registry (Your Note of 11/28/84)—INFORMATION

Intermediary Procedures staff met with FDA, OLP, and BERC on November 16 to discuss data exchange requirements for the registry.

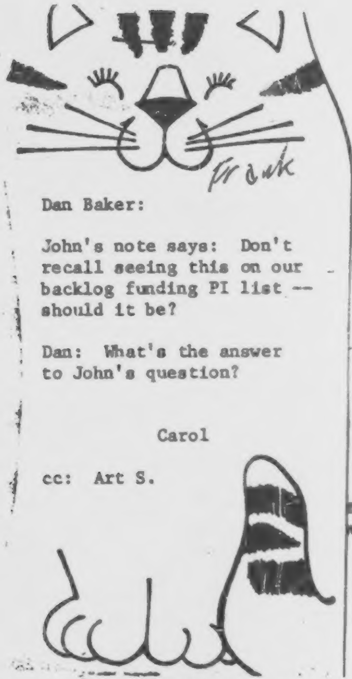
In view of HSQ's refusal to be involved in the project we have decided to have intermediaries gather the needed data. HSQ does have a valid position in that pacemaker leads are not routinely reviewed and they hope to eventually reduce pacemaker review. We plan that where a diagnosis or surgical procedure code indicates pacemaker-related care the intermediary's system will generate a letter to the hospital seeking supplemental data for inclusion on the registry. This appears to be less expensive than incorporating required data elements into the billing process.

The intermediary will accumulate the data and transmit it to central office (BPO) periodically via the personal computer network or a similar process, and BPO will forward the data to FDA.

We are still analyzing what use of the data can be made in the bill process. We think we may be able to use the registry to identify prior implants within the warranty period, but this may require a duplicate data base maintained in HCFA or at the intermediary.

We are preparing contractor instructions.

Carol
Carol J. Walton



Frank

Dan Baker:

John's note says: Don't recall seeing this on our backlog funding PI list -- should it be?

Dan: What's the answer to John's question?

Carol

cc: Art S.

Carol— Frank Don't recall seeing this on our backlog funding PI list— should it be

maker Registry (Your Note of 7/11/84)—

3 12/21

ry, through the FDA, to provide a registry of all
which payment is made under Medicare. The

6. geographic location
7. physician name
8. hospital or other provider
9. warranty information (no precise guideline)
10. anything else the Secretary deems appropriate

All of the above items (except possibly 10) are available to the medical review entity. The intermediary would have access to only 4, 5, 6, 7, and 8 in the bill process. We have suggested informally at the staff level to HSQ that the PRO would be a more suitable data collection agent than the intermediary, and that the PHDDS from the PRO to HSQ or some other PRO to HSQ reporting mechanism would be a better reporting vehicle than PATBILL/UNIBILL. They are still considering this.

NOTE: PATBILL/UNIBILL now contains the ICD-9-CM procedure code to indicate pacemaker insert, which alerts the PRO to develop, and current instructions require medical review of all such cases.

Carol

Carol J. Walton

cc: John Jansak

Carol—
[illegible]
Don't recall
seeing this in
our backlog for big
PI list— should
it be
B 12/21

JUL 23 1984

TO : John C. Berry

SUBJECT : Section 2304 - Pacemaker Registry (Your Note of 7/11/84)— INFORMATION

Section 2304 requires the Secretary, through the FDA, to provide a registry of all pacemaker devices and leads for which payment is made under Medicare. The registry must include:

1. manufacturer
2. model
3. serial number
4. recipient
5. date
6. geographic location
7. physician name
8. hospital or other provider
9. warranty information (no precise guideline)
10. anything else the Secretary deems appropriate

All of the above items (except possibly 10) are available to the medical review entity. The intermediary would have access to only 4, 5, 6, 7, and 8 in the bill process. We have suggested informally at the staff level to HSQ that the PRO would be a more suitable data collection agent than the intermediary, and that the PHDDS from the PRO to HSQ or some other PRO to HSQ reporting mechanism would be a better reporting vehicle than PATBILL/UNIBILL. They are still considering this.

NOTE: PATBILL/UNIBILL now contains the ICD-9-CM procedure code to indicate pacemaker insert, which alerts the PRO to develop, and current instructions require medical review of all such cases.

Carol
Carol J. Walton

cc: John Jansak

[JAN 3 1985]

PRIORITY II

DUE: 1/18/85

Control: OPOP
Sign: CW
CNO:
8501048279

① FD
② AS
③ TB

NOTE TO: Carol Walton

SUBJECT: Pacemaker Registry

Your note of 12/12/84 presumes a level of knowledge beyond mine. Please give me a 1 or 2-pager starting with background on exactly what the law requires and then a brief overview of the issues. Please tie this into other recent actions on monitoring and reimbursement.

My objective was to get a complete overview of all pacemaker related activities and assure that we are carrying out all operational requirements.

John C. Berry

cc:
John Jansak

ROUTING AND TRANSMITTAL SLIP

Date 1/17/85

TO: (Name, office symbol, room number, building, Agency/Post)	Initials	Date
1. ~~Dan Baker~~ Frank Spruill		
2. Josephine		
3.		
4.		
5.		

☐	Action	☐	File	☐	Note and Return
☐	Approval	☐	For Clearance	☐	Per Conversation
☐	As Requested	☐	For Correction	☐	Prepare Reply
☐	Circulate	☐	For Your Information	☐	See Me
☐	Comment	☐	Investigate	☐	Signature
☐	Coordination	☐	Justify	☐	

REMARKS

Dan:

This is a good note -- clear and concise. What is our schedule for getting procedures to the intermediaries for collecting pacemaker information?

Carol Walton

DO NOT use this form as a RECORD of approvals, concurrences, [illegible]als, clearances, and similar actions

FROM: (Name, org. symbol, Agency/Post)	Room
	Ph

5041-102

OPTIONAL
Prescribed
FPMR (41

JAN 17 1985

TO : John C. Berry

SUBJECT : Your Request for an Overview of Pacemaker Activities (Your Note of 1/3/85)—INFORMATION

There are three basic issues with respect to pacemakers.

1. Are we paying too much for implants and reimplants that are needed, i.e., how much has technology reduced the cost of surgery and is the program benefitting from lower charges?
2. The Deficit Reduction Act requires FDA to establish and maintain a registry for pacemaker devices and leads.
3. Where the cause of a reimplant is faulty or warranted original equipment, can we shift cost to the manufacturer by avoiding or recovering payment?

With respect to (1) the BQC is planning a study to measure the impact of technology. We have reviewed the study proposal but we are not operationally involved, at least until study results are known.

With respect to (2) OPOP has lead responsibility. The Deficit Reduction Act requires the Secretary to provide a registry of all pacemaker devices and leads for which payment is made under Medicare. The Act specifies the data elements to be included. We initially proposed that since all of the data elements would be available during medical review (and few would be available normally in the hospital billing process) the PRO should collect the data as part of the medical review process. HSQB convinced us otherwise. We are developing procedures for intermediary collection of the data and for transmission of the data through HCFA to the FDA. Our plans also call for FDA to provide sufficient data about product recalls to identify beneficiaries and manufacturers where the manufacturer may be liable for use in procedures developed to implant the process discussed in (3). FDA is agreeable.

With respect to (3) OPA has lead responsibility. HCFA does not have the authority to withhold payments and the only method currently available to collect on warrantees or recalls is to sue the manufacturer (e.g. Medtronics). This is costly and cumbersome. BPO has proposed that regulations be changed to permit offset against the reimbursement to the hospital that purchased the pacemaker. This would encourage the hospitals to collect on the warranty and would be an expeditious method to recover the warranty amount available from the manufacturer. BERC has not favored this approval because it would require adjustments to the prospective payment system. However, without authorization to make recoveries on available warranty funds, HCFA will not be able to do so. OPA plans to initiate discussions with BERC senior staff in this area.

Carol
Carol J. Walton

cc: John Jansak

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care
Financing Administration

Refer to: FQA-722

Memorandum

Date JAN 23 1985

From Director
Bureau of Eligibility, Reimbursement and Coverage
Health Care Financing Administration

Subject Implementation of Pacemaker Provision (Section 2304) of the "Medicare and Medicaid Budget Reconciliation Amendments of 1984"—INFORMATION

To Mr. Robert C. Eccleston
Assistant Director of Intergovernmental Liaison
Center for Devices and Radiological Health
Food and Drug Administration

The purpose of this memorandum is to confirm certain understandings reached between Mr. Katz of my staff and you regarding our agencies' respective areas of responsibility for subsection (c) of section 2304.

Subsection (c), the registry provision, consists of two separate programs--(1) the establishment by FDA of a pacemaker registry, including the imposition of a reporting requirement on Medicare providers and suppliers (1862(h)(1)(A) and (B)), and discretionary authority to make Medicare payment for initial implants and replacements conditional upon compliance with the registry requirements, (1862(h)(1)(C) and (h)(4)(A)), due by January 1, 1985; and (2) discretionary authority (1862(h)(2), (3) and (4)(B) and (C)) to deny Medicare coverage and payment to providers for pacemakers or leads not submitted for inspection and testing to the manufacturer, if so required.

We have agreed that, while the establishment and maintenance of the registry is clearly delegated to the FDA, HCFA would be responsible for rules with respect to the provision's impact on providers and physicians under Medicare. One Medicare provision ((h)(1)(C)) related to the registry is mandatory—physicians and providers are required to supply information to the FDA for the pacemaker registry for both initial implants and replacements. Another provision, (h)(4)(A)), although prefaced by a discretionary "may," enforces the mandatory provision by authorizing withholding of payment to physicians or providers who fail to submit information to the registry. While this latter provision is discretionary, we think it should be put into regulations. Although we already have broad regulatory authority to withhold payment to providers and suppliers who do not comply with various reporting requirements, we think enforcement of the new registry provision should be supported by a discrete regulatory provision that authorizes the withholding of Medicare payment when the reporting requirement is not complied with.

With regard to the discretionary inspection program, section 1862(h)(2) of the Medicare law will now permit the Secretary to require providers to: (A) return to manufacturers for testing any pacemaker or lead implanted or replaced; and (B) not charge beneficiaries if the devices have not been returned. Section 1862(h)(3) permits the Secretary to require manufacturers to: (A) test the devices (presumably at the manufacturer's expense); and (B) report the results to the provider, together with any warranty information, and require that FDA personnel be present at the testing if it is suspected that the pacemaker or lead had malfunctioned. Section

1862(h)(4)(B) and (C) permit the Secretary to deny payment under Medicare if the provider or the manufacturer fails to perform any of its responsibilities under this provision.

Although the enforcement provisions of section 1862(h) have clear implications for Medicare coverage and reimbursement for services, they are dependent for their application on the nature and efficacy of the proposed FDA pacemaker registry. Thus, development of HCFA's portion of the necessary regulations will be largely dependent on FDA action in this area. Consequently, we agree that responsibility for development of those regulations be jointly held by FDA/HCFA, with FDA the lead agency. HCFA would be responsible for supplying to FDA the necessary conforming regulations to Title XVIII with regard to 1862(h)(1)(C); (h)(2)(B); (h)(4)(A), (B) and (C) for inclusion by FDA with its regulations establishing the pacemaker registry.

We also wish to inform you that we plan to defer development, or at least publication, of regulations dealing with the portion of 1862(h)(2)(B) and (h)(4)(B) and (C) which would deny payment under Medicare in cases in which providers or manufacturers fail to submit pacemakers for testing if ordered to do so. This provision is couched in the discretionary "may." In addition, it obviously requires more extensive consultation and preparation than the registry provision. Moreover, its implementation and degree of specificity will depend on the actual functioning (not just regulatory requirements) of the pacemaker registry. The legislation seems to imply that some experience with the actual operation of the registry is expected, since it refers to information received from the registry as a basis for requiring that FDA personnel be present at the testing of a pacemaker or lead.

Our current pacemaker activities may well affect how this provision may be developed. These activities include the ultimate disposition of the Medtronic lead issue and the data and actions flowing from Professional Review Organization (PRO) 100 percent review of Medicare claims for pacemaker implants. It is possible that these activities will reduce or eliminate the need for any elaborate regulatory provision in this area. Consequently, we decided that at least the Medicare portion of this provision should be deferred until such time as we have a clearer view of what will need to be done and how the registry will affect our ability to do it.

We would appreciate your reaction to these plans and understandings. If you have any questions or alternative suggestions or recommendations, please contact Mr. Stanley Katz of my staff as soon as possible. (He can be reached by telephone at 594-8561.) If you agree that these plans and understandings are reasonable and feasible, please consider this memorandum to be an informal understanding between our two agencies as to how we will proceed.

Henry R. Desmarais

Henry R. Desmarais, M.D.

[illegible]

Villforth
Benson

cc: Cathy Norcio

List of other proposed attendees:

Eccleston, Lenahan	Goldstein/Suydam
Gundaker	Pahnoeller
Andersen	

NOTIFICATION OF MEETING WITH OFFICE OF CENTER DIRECTOR

Date: 1/24/85 **Time**: 1:00 **Place**: T-503

Contact Person: Bob Eccleston/Donna Lenahan

Subject: Pacemaker Registry

Background: (See Attachment)

Goal of Meeting (what do you want OCD to do?): (See Attachment)

Attendees actually present:

Results of Meeting (contact person to complete, continue back side if necessary):

Prepared by: ______________________ Date: ____________

Directions: 1. Schedule meeting with OCD, 2. Complete this form, 3. Distribute copies as indicated 4. Record results of meeting 5. [illegible]

Background

Last July, Congress enacted a law directing FDA to set up a national registry for pacemakers and pacer leads. At the Center's "go away" at USPHS last summer, OMS & Exec Sec were asked to develop an implementation strategy. A CDRH task force (with GC & OLI representation) was formed to carry out this assignment. Based on internal discussions and meetings with Congressional and HCFA staff, the task force submitted its report to Center management in November.

While the statute requires the registry and supporting regs to be in place by Jan. 1, 1985, there's general acceptance of the fact that this deadline is unrealistic. However, in a meeting with FDA, members of Sen. Heinz's staff warned of their intent to monitor FDA's progress, and noted the possibility of hearings.

The major stumbling block and cause for delays has been a reluctance by HCFA to commit to any role which, given the thrust and intent of the legislation, is critical. In recent talks with HCFA, they have verbally agreed to assume certain functions. This commitment is reportedly to be formally stated in a memo from Dr. Desmarais (head of HCFA's Bureau of Eligibility, Reimbursement, and Coverage), which should reach CDRH within the next 2 weeks. Given this assurance, and HCFA's reciprocal interest in establishing an interagency work group to work out the specific details, it is appropriate to discuss with Center management the outstanding issues related to this law and the decisions that need to be made before the "next steps" can be taken.

(For additional background, see the attached Executive Summary from the final task force report.)

Goals of the Meeting

1. To become familiar with the specific details of the law, as well as the issues that need resolution, and the several new developments that may impact on the Center's implementation decisions.

2. To decide what Center component should serve as the overall coordinator of this activity.

3. To agree to the recommended registry-related responsibilities and activities of various Center components and, if necessary, re-align these responsibilities.

4. To decide on the best mechanism for establishing and maintaining the registry, i.e., an in-house effort or extramural contract.

5. To give guidance on the timing and vehicle for informing FDA management of the Center's plans for implementing the law and working with HCFA.

EXECUTIVE SUMMARY/TABLE OF CONTENTS

Summary of Text Page(s)

- What is the purpose of the paper? 1

The enclosed document, prepared by a Center-chaired task force, is intended to provide the history and events leading up to the passage of the cardiac pacemaker registry legislation, and to propose an "operational blueprint" for carrying out the law.

- What are the key elements of the law? 1-3

The "Deficit Reduction Act of 1984" (P.L. 98-369) was enacted on July 18, 1984. Section 2304 of the Act (which amends the Social Security Amendments) requires two major actions be taken by the Department in connection with Medicare reimbursement for pacemaker and pacer lead procedures. First, HCFA is to review its current post-implant monitoring guidelines to curb claims for too frequent or unnecessary monitoring. HCFA must also review present physician payment schedules, and hospital charges associated with pacemaker procedures are to be reviewed by the Prospective Payment Assessment Commission.

Secondly, FDA is to establish a nationwide registry of all pacemakers and leads for which Medicare payment is made. Data such as the date and location of the procedure, type, model, and serial numbers of the devices, and warranty information are to be collected. The goal of this registry is threefold: (1) to assist the Secretary in making reimbursement decisions; (2) to track pacemaker performance; and (3) to determine when testing of allegedly malfunctioned pacemakers should be performed. The Act specifies that the registry and implementing regulations shall be in effect by January 1, 1985.

- What events led to the passage of the Act? 4-6

In 1982, the Senate Special Committee on Aging released a report, "Fraud, Waste, and Abuse in the Medicare Pacemaker Industry," which cited problems regarding pacemaker performance, cost, warranties, qualifications of implanting physicians, and pacemaker sales practices. In the report, the Committee proposed a number of actions for HHS/FDA, VA, SEC, and recommended legislation for a nationwide pacemaker registry. In July 1983, Senator Heinz and Congressman Wyden introduced virtually identical bills which provided the basis of the law now on the books.

- How does HCFA presently reimburse for pacemaker implants? 6

In view of the cost-containment orientation of the law, the paper examines current HCFA reimbursement policies and procedures. Under the new Diagnostic Related Group/Prospect Payment System (DRG/PPS), pacemaker devices are no longer paid for separately; their costs are factored into the expenses of the entire treatment program, which are reviewed by Professional Review Organizations (PRO) for medical necessity, appropriateness, and quality of treatment. In this connection, HCFA is presently conducting 100% reviews of pacemaker implantations. The PRO's are also currently collecting warranty information on a limited basis. (Note that similar information is also gathered by intermediaries under contract with HCFA, e.g., Blue Cross/Blue Shield.)

- How can the registry data be used? 7-9

As noted earlier, the registry data is to be used principally to give HCFA a "window" on pacemaker procedures, and as an adjunct to its reimbursement decision-making. It is expected that approximately 120,000 pacer implants/re-implants (along with lead implants) and 30,000 lead replacements will be reported to the registry each year. Each report will contain a minimum of 9 and perhaps as many as 20 data elements per report. Although the registry is not an adverse effects reporting system like DEN and MDR, it can serve as a useful tool in monitoring the long-term performance of pacemakers. The registry can also identify defective pacemakers still under warranty so that Medicare payments can be withheld.

- Are there other pacemaker registries after which FDA's registry could be modeled? 9

A five-Center registry supported by FDA from 1974-1980 is still in operation, but is oriented somewhat differently in terms of the type of data collected. In 1982, ECRI established a National Implant Registry which, on a subscription basis, maintains an informational file on pacemaker patients, pacemaker recalls, corrective actions, etc. for hospitals. Also in 1980, the VA initiated a Pacemaker Surveillance System to provide transtelephonic monitoring of patients and cardiology consultation to referring the VA medical centers. In reviewing the focus and scope of these registries, it appears that none are suitable in their present form to meet the requirements of the law. It should be noted that as many as five private sector organizations (including the first two noted above) have written the Center indicating an interest in assisting FDA in maintaining the registry.

- What are the implementation options? 9-11

Initially, the Task Force conceived of three possible options for establishing and maintaining the registry. These were based on the premise that the registry would serve as the vehicle for data collection and analysis. They were: (1) an in-house effort; (2) an extramural contract; and (3) use of HCFA's PRO system to collect the data, with FDA to provide long-term performance trend analyses. The Task Force felt that having HCFA operate the registry was the option of choice because it would remove FDA from the middle of the reporting chain, and, since HCFA now collects much of the information required by law, would avoid re-inventing the wheel.

Recent discussions with HCFA staff have led to a preliminary agreement that HCFA assume lead responsibility for collecting the data, and that FDA will maintain and analyze the data base. The idea of using the PRO system has been discarded, in favor of data collection by the approximately 60 intermediaries which handle the agency's claims processing. The data would be maintained as part of HCFA's permanent records and transmitted periodically to FDA for analysis.

FDA would then use the data to identify and analyze generic performance problems with pacemakers and leads. The options for setting up and running the registry are basically the same as the first and second options above. The chief advantages of the contract route -- which the Task Force favors -- are that it would avert a drain on in-house resources (although some in-house scientific review would still be needed), and it would be in keeping with OMB's A-76 Directive, which urges greater use of Federal service contracts.

- Is a special committee needed to advise and oversee the Center in establishing the registry? 11

The Task Force believes so. Such a group should be charged with the overall coordination of registry activities. Since the present composition of the Task Force does not include HCFA representatives, it is felt that a new "coordinating committee" should be formed, with HCFA representation. Public input into the development of the registry and the underlying regulations can be obtained through the administrative rulemaking process, through discussions with constituencies represented on the Center's Cardiovascular Devices Panel, and through informal contacts with appropriate outside organizations.

- What about funding? 11-13

Although no appropriation accompanied the legislation, the Senate Appropriations Committee recommended that FDA file a supplemental request to its FY 85 budget. Departmental efforts to secure additional funding have been made on two tracks. The first is a supplemental request for $1.2 million to be added to the FY 85 budget. The second is the inclusion of a line item in FY 86 budget for 11 FTE's and $1.2 million. Irrespective of the implementation option chosen, a formal agreement with HCFA is advisable. There is some thinking that the data collected could be sold to hospitals, cardiology organizations, etc., to help defray some of the registry implementation costs.

- How much time is involved in getting the registry up-and-running? 13-15

One of the first steps is to negotiate an interagency agreement or memorandum of understanding with HCFA in order to clearly define each agency's responsibilities. Three to six months is estimated as the time needed to complete negotiations and obtain all the necessary clearances. Although the Task Force recognizes and is concerned about the time needed to consummate an agreement, we support the idea of a formal working agreement. HCFA has suggested keeping the working arrangements on an informal basis.

Insofar as regulations development is concerned, it is unclear whether FDA alone, HCFA alone, or an interagency effort is required to issue implementing regulations. The Center's FY 85 regulations plan includes having a proposed rule out of CDRH in June and out of FDA by September of next year.

Regarding establishment of the actual registry, if we elect to go the contract route, it is expected that final awarding of a contract would require 4-6 months.

- Will there be any impact of the registry requirements on existing regulations? 15-16

There are three potential areas of the Center's device program that must be taken into account as the registry regulations are developed. First, current GMP regulations require investigations and records of complaints, which could include explanted pacemakers. Since the registry legislation calls for providers to return explanted pacers to manufacturers, some attention must be given to this issue. The second area is MDR. Failures of pacemakers, especially in "pacemaker dependent" patients, might meet the reporting criteria contained in the MDR rule. Again, the registry regulations must be developed so as to not overlap or conflict with current MDR requirements. Finally, the registry regulations should specifically address pertinent FOIA issues given the confidential nature of the data.

- What are Congress' expectations regarding the registry? 16

From conversations with staff from the Senate Committee on Aging, it is clear that Senator Heinz will keep a watchful eye on FDA's progress in carrying out this law. Although there is general agreement between FDA and the Committee that the January 1, 1985 deadline is unrealistic, the Committee has not foreclosed the possibility of oversight hearings early in 1985. In view of this, the Task Force favors the idea of sending a letter report to Senator Heinz and other appropriate Congressmen that describes our implementation plans. It should also be noted that the existence of this legislation and the recent hearings on the Medtronic pacemaker lead situation has spawned even wider Congressional interest in the subject of Medicare reimbursement for defective products, particularly pacemakers.

- What does the implementation "blueprint" look like? 16-17

The Task Force believes that implementation can be viewed in a phased approach. Phase I, for example, would include actions such as establishing a Coordinating Committee, soliciting input from HCFA and outside groups, and initiating interagency negotiations with HCFA. Phase II would include early work to develop the implementing regulations, initiating the contract process (if necessary), and preparing an implementation report for transmittal to the Congress. Phase III calls for publication of the proposed regulation. Phase IV includes promulgation of the final regulations and, if necessary, the development of educational initiatives to inform the medical community and the pacemaker industry about the specific requirements contained in the regulations. The Task Force anticipates that Phase I could be accomplished during the first quarter of FY 85; Phase II during the second quarter; Phase III during the fourth quarter; and Phase IV during the third quarter of FY 86.

- Is their general consensus within the Center on this strategy? 17-19

This implementation paper has been shared with Center senior staff for review and comment. It appears that there is general unanimity on the approach to this new initiative.

- What are the Task Force's recommendations? 19-20

Eight separate proposals have been made by the Task Force, all of which are designed to take the Center and HCFA into the next implementation phase, i.e., to solidify a working arrangement between both agencies, and to "iron out" the mechanics of collecting the required data, "feeding" it to the registry, and providing some performance trend analysis. Based on your decisions, OMS will take the lead "coordinator" role in proceeding to the next phase of implementation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

6325 Security Boulevard
Baltimore, MD 21207

JAN 25 1986

Ms. Donna Lenahan
FDA 5600 Fisher Lane
Rockville, Maryland 20857

Dear Ms. Lenahan:

The enclosed form is a draft which will be used to obtain from the hospital information needed for the Pacemaker Registry. Please review and inform us of any changes or additional information which should be included, particularly in reference to warranties.

If you have any questions please contact Marguerite Fatherly on area code 301-497-2599.

Sincerely,

Frank Spruill

Frank Spruill, Chief
Intermediary Procedures
Division of Methods and Systems Procedures
Office of Program Operations Procedures
Bureau of Program Operations

Enclosure

Name of Hospital
Hospital
Address

1. Patient: Date:
2. HIC ____________
3. Dates of Confinement ____________

The medical information on the claim you recently submitted for the above confinement indicates pacemaker related services. Section 2304 of P.L. 98-369 requires that we obtain from you the information listed below for inclusion in the Food and Drug Administration's Pacemaker Registry. Your response to this request within 30 days of the date of this letter is appreciated.

Identification number of physician performing the pacemaker related procedure: 4. ____________

Identification number of physician ordering the pacemaker related procedure: 5. ____________

Date of pacemaker-related procedure implant: 6. ____________

Pacemaker information:

	Component	Mfgr	Model	Serial Number
a.	Pulse Generator	7)	8)	9)
b.	Atrial Lead	10)	11)	12)
c.	Ventricular Lead	13)	14)	15)
d.	Bipolar Lead	16)	17)	18)

If this patient previously had a pulse generator, which was explanted during this stay provide the following:

If available provide:

Date of pacemaker explant 19) ____________

	Component	Mfgr	Model	Serial Number
e.	Explanted Pulse Generator	20)	20)	22)

ROUTING AND TRANSMITTAL SLIP Date 2/6

TO: (Name, office symbol, room number, building, Agency/Post) | Initials | Date

1. Glen
2. Called into Donna on
3. 2/11/85.
4.
5.

Action	File	Note and Return
Approval	For Clearance	Per Conversation
As Requested	For Correction	Prepare Reply
Circulate	For Your Information	See Me
Comment	Investigate	Signature
Coordination	Justify	

REMARKS

Please comment on attached by 2/13.

Thanks

DO NOT use this form as a RECORD of approvals, concurrences, disposals, clearances, and similar actions

FROM: (Name, org. symbol, Agency/Post)
Donna

Room No.—Bldg.

Phone No.
443-5807

5041-102

OPTIONAL FORM 41 (Rev. 7-76)
Prescribed by GSA
FPMR (41 CFR) 101-11.206

1981 0 - 361-529 (151)

Health Care Financing Administration

6325 Security Boulevard
Baltimore, MD 21207

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Chief
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

6325 Security Boulevard
Baltimore, MD 21207

JAN 2 5 1985

Ms. Donna Lenahan
FDA 5600 Fisher Lane
Rockville, Maryland 20857

Dear Ms. Lenahan:

The enclosed form is a draft which will be used to obtain from the hospital information needed for the Pacemaker Registry. Please review and inform us of any changes or additional information which should be included, particularly in reference to warranties.

If you have any questions please contact Marguerite Fatherly on area code 301-497-2599.

Sincerely,

Frank Spruill, Chief
Intermediary Procedures
Division of Methods and Systems Procedures
Office of Program Operations Procedures
Bureau of Program Operations

Enclosure

Name of Hospital
Hospital
Address — Add

1. **Patient:** **Date:**
2. HIC ____________
3. Dates of Confinement ____________

The medical information on the claim you recently submitted for the above confinement indicates pacemaker related services. Section 2304 of P.L. 98-369 requires that we obtain from you the information listed below for inclusion in the Food and Drug Administration's Pacemaker Registry. Your response to this request within 30 days of the date of this letter is appreciated.

Identification number of physician performing the pacemaker related procedure: 4. ____________ (Do we need the name?)

Identification number of physician ordering the pacemaker related procedure: 5. ____________

Date of pacemaker-related procedure implant: 6. ____________

Pacemaker information:

	Component	Mfgr	Model	Serial Number
a.	Pulse Generator	7)	8)	9)
b.	Atrial Lead	10)	11)	12)
c.	Ventricular Lead	13)	14)	15)
~~d.~~	~~Bipolar Lead~~	~~16)~~	~~17)~~	~~18)~~

If this patient previously had a pulse generator or lead, which was explanted or replaced during this stay provide the following:

If available provide:

Date of ~~pacemaker~~ explant or replacement 19) ____________

	Component	Mfgr	Model	Serial Number
e.	Explanted Pulse Generator	20)	20)	22)
f.	Atrial lead	23)	24)	2[illegible]
g.	ventricular lead	[illegible]	2[illegible])	)

ROUTING AND TRANSMITTAL SLIP

Date

TO: (Name, office symbol, room number, building, Agency/Post)	Initials	Date
1. Glenn Rahmoeller		
2.		
3.		
4.		
5.		

☐ Action	☐ File	☐ Note and Return
☐ Approval	☐ For Clearance	☑ Per Conversation
☐ As Requested	☐ For Correction	☐ Prepare Reply
☐ Circulate	☐ For Your Information	☐ See Me
☐ Comment	☐ Investigate	☐ Signature
☐ Coordination	☐ Justify	

REMARKS

2/13/85
I discussed my comments c̄ Donna [illegible] (Bob Eccleston is out today).

DO NOT use this form as a RECORD of approvals, concurrences, disposals, clearances, and similar actions

FROM: (Name, org. symbol, Agency/Post)	Room No.—Bldg.
Eccleston	Phone No. 49

5041-102

*U.S.GPO 1983-421-529/320

OPTIONAL FORM 41 (Rev. 7-76)
Prescribed by GSA
FPMR (41 CFR) 101-11.206

FEB 5 1985

et tomorrow in my
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distribution to the
e Directors summarizing
that were made at the
, culminates the work

on about where we go from
s meeting.

FEB 5 1985

NOTE TO: Donna Lenahan
Alan Andersen
Glen Rahmoeller

As we confirmed with you, we're scheduled to meet tomorrow in my office at 10:00. The main purpose of the session is to discuss several recent events related to the pacemaker registry and how best to respond to them. One item is the memo we recently received from HCFA (copy attached) which was spell out the Agency's commitment based on the negotiations that have taken place over the last few months. We need to respond to HCFA's memo and a draft response is also attached.

Another item for discussion is OMB's recent decision regarding FDA's resource request in support of the registry. At a one-on-one with the Commissioner last week, John Villforth and Jim Benson discussed the dilemma of having a legislative mandate without the necessary resources. Dr. Young, in turn, asked that we supply him with background information about the law and what we're obligated to do as well as the level of resources needed to the job. Also attached is a draft memo back to the Commissioner with this information.

Finally, attached is the memo I've drafted for distribution to the Pacemaker Registry Task Force and certain Office Directors summarizing the recent events noted above and the decisions that were made at the briefing with John last month; this, in effect, culminates the work of the Task Force.

These issues, along with some general discussion about where we go from here is what I'd like to focus on at tomorrow's meeting.

Bob Eccleston

Attachments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

DRAFT
FEB 5 1985

. NOTE TO: Cardiac Pacemaker Registry Task Force

This note is to update you on the actions that have occurred relating to the pacemaker registry since the Task Force report was submitted to the Center management last month.

o On January 24, various members of the task force briefed Mr. Villforth, Mr. Benson, and a number of Office Directors on the basic requirements of the new law, and on the implementation strategy developed by the task force which is embodied in the Task Force report. At the briefing, the following decisions were made:

- An interagency work group, comprised of FDA and HCFA representatives should be established to work out the various implementation details. The charge to such a group should be guided by a formal interagency agreement or MOU. To this end, Mr. Villforth has agreed to write the head of HCFA's Bureau of Eligibility, Reimbursement and Coverage suggesting that such a group be formed and requesting names of HCFA staff who can represent the Agency in these ongoing discussions (see Tab A).

- Establishment and maintenance of the registry, along with performance trend analyses of pacemakers and pacer leads be accomplished via contract rather than an in-house effort.

- OMS should assume the oversight/coordinator role for the duration of the discussions with HCFA, up until specific operational activities are initiated by the various Center offices. At that point, the "lead office" concept will take effect for registry-related activities.

- The Center should investigate the "cash cow" potential and "market" for product performance reports based on the actuarial analyses performed using registry data, e.g., within the cardiology community, the VA, etc.

- At about the time the Task Force Report was completed, FDA received word from the Department's Budget Review Group (BRG) regarding the Agency's supplemental and FY 86 funding request related to the registry. BRG approved the $1.2 million supplemental funding request, but disapproved the concomitant request for 11 FTE's. BRG, however, agreed to incorporate FDA's full request (i.e., dollars and people) in the FY 86 budget. Unfortunately, as a result of the new budget freeze, OMB recently rejected both HHS requests and indicated that no appeals will be entertained.

  This issue was brought to the attention of the Commissioner by Mr. Villforth and Mr. Benson during a recent one-on-one meeting. The Commissioner asked for additional background information and indicated his willingness to explore ways for securing the needed resources (see memo at Tab B).

In closing, we would like to once again express our thanks to each of you for your contribution to Task Force deliberations. The briefing for Center management was well received and reflects the hard work and energy you put into this activity. Although this marks the end of the Task Force's work, many of you may be called on as the Center proceeds to the next phase(s) of implementation.

Robert C. Eccleston

Donna Lenahan

cc: Mr. Villforth
Mr. Benson
Mr. Gundaker
Mr. Britain
Mr. White
Dr. Mohan
Mr. Arcarese
Ms. Suydam

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Memorandum

DRAFT
FEB 5 1985

Date

From Director
Center for Devices and Radiological Health

Subject Cardiac Pacemaker Registry Legislation -- ACTION REQUESTED

To Director
Bureau of Eligibility, Reimbursement and Coverage
Health Care Financing Administration

I am writing in follow up to your January 23 memorandum to Mr. Robert Eccleston of my staff regarding the cardiac pacemaker registry provisions of the "Deficit Reduction Act of 1984." After a careful reading of your memo, we are somewhat concerned that it failed to fully reflect the agreements that were reached by staff of our two organizations.

Implementation Responsibilities

In a recent briefing on the pacemaker registry legislation by Mr. Eccleston and others, I was advised that during our negotiations with representatives of BERC and other HCFA components, there was considerable discussion on how the data prescribed by the law should be collected and by whom. While the Act clearly requires physicians and providers to supply certain implant/explant and warranty information to FDA to incorporate into the registry, it is my understanding that BERC agreed to serve as the collector of that information. This data collection function would be carried out ✓ through the already-established network of third-party intermediaries which HCFA presently has under contract. The data would then be transmitted in an agreed-upon format to us to use in monitoring the performance of pacemakers and pacer leads. Implementing this aspect of the law in this way has two salutory effects: first, it builds on an already-established reporting scheme which, as I understand it, will require only slight modifications to your existing contracts; and second, it reduces the Department's costs in administering the law.

I believe it is important to maintain the momentum that our staffs have established. To that end, I would like to suggest that an interagency task force, comprised of appropriate HCFA and FDA staff, be created to work out a formal working agreement and specific implementation details, many of which were touched on in your memo. Should you agree with this suggestion, I would ask that you designate 3-5 persons to represent HCFA in the areas of data collection, program operations, and regulations development. Please forward the names of your designees to Ms. Donna Lenahan of our Office of Management and Systems, whom we have assigned to oversee the next phase(s) of this project.

Reportedly, the interest in this activity is likely to continue, particularly on the part of the Senate Special Committee on Aging. In view of this and the fact that the statutory deadline is now past, I would propose that we inform the Congress on the progress we have made thus far and our future plans. This might best be accomplished by a letter-report to Senator Heinz, perhaps co-signed by appropriate officials of each of our agencies. As Mr. Eccleston indicated to Mr. Stan Katz in a recent telephone conversation, we are willing to take the lead in drafting such a report and share it with you for review and sign-off. It would be helpful, however if your staff could provide us with a written description of the data collection scheme HCFA is proposing to use that we could incorporate into the report to the Senator.

New Uncertainties About the Registry

I should mention that shortly after this legislation was enacted, FDA submitted a request for supplemental funding to its FY'85 budget and a specific appropriation in its FY 86 budget plan. We have just learned that these requests have been disapproved by OMB due to the recently-imposed budget freeze. We have discussed this situation with the FDA Commissioner, ~~stressing our concern over the possibility of having to take on a new activity with an already strained budget~~ and. It is unclear at this point what might be done through internal reprogramming or through the budget appeals process to secure the resources needed to support this activity.

In addition to an unclear budget picture is the impact of the new Executive Order on regulatory initiatives. As I'm sure you are aware, OMB is now authorized to review and approve or disapprove newly-planned regulations before formal action on them begins. ~~I should note that in FDA's submission to the Department, the pacemaker registry regulations were included as an item for HHS and OMS review. So the possibility exists that~~ [illegible] the required rgulations that would ~~to underpin the~~ and the registry ~~could be at risk of veto by OMB~~ — may be reviewed, and [illegible] and possibly rejected, by OMB.

We appreciate the efforts you and your staff have made to date, and we look forward to working out an effective implementation plan that will help us both fulfill our respective responsibilites under the law.

John C. Villforth

cc: Dr. Young
Mr. Meyer
Mr. Wetherell
Mr. Benson/Mr. Eccleston
Mr. Goldstein
Ms. Suydam/Ms. Lenahan

DEPARTMENT OF HEALTH & HUMAN SERVICES   Public Health Service

Memorandum

Date

From   Director
Center for Devices and Radiological Health

Subject   Funding for Cardiac Pacemaker Registry -- INFORMATION

DRAFT
FEB 5 1985

To   The Commissioner
Through: Exec Sec ______

At our one-on-one last week, Jim Benson and I mentioned OMB's recent decision to disapprove the Agency's funding requests to support the cardiac pacemaker registry activities. You asked that we provide you with background information on what the pacemaker registry legislation requires of us, and when and what level of resources are needed to carry out this new mandate. Let me begin by recapitulating the facts.

In passing the "Deficit Reduction Act of 1984," the Congress failed to appropriate funds specifically for the pacemaker registry provisions. Because our current budget cannot accomodate any new activity, the Agency filed with the Department's Budget Review Group (BRG) a supplemental request for $1.2 million to the FY 85 budget. In addition, we requested that $1.2 million and 11 FTE's be included in FDA's FY 86 budget. Despite approval by the BRG, OMB rejected both proposals.

The law basically requires the following actions:

o FDA must establish a national registry for pacemakers and pacer leads to serve as a repository for certain implant/explant and warranty information. Submission of this information by physicians and providers, which relates only to Medicare pacemaker procedures (about 80% of those performed in the U.S.), would be a condition for Federal reimbursement.

o Explanted pacemakers and leads may be required to be returned to the manufacturer for testing which, again, could be linked to reimbursement. FDA is also authorized to participate in such testing on an discretionary basis.

o FDA must develop regulations to carry out the above activities.

In an attempt to keep implementation costs as nominal as possible, and because of the obvious linkage between this law and Medicare reimbursement activities, we have recruited help from HCFA in the areas of regulations development and data collection (see memoranda at Tab A).

Our joint efforts with HCFA notwithstanding, it is apparent that additional resources will be required to carry out our part of the law. At Tab B are two charts -- one depicting the specific requirements of law, and the second -- in flow chart form -- which illustrates our legislative implementation strategy.

Since we must immediately begin to develop the regulations and because we favor going the contract route for establishing the registry, I believe it is necessary to make the requisite resources available at the front end of this activity, rather than "staging" the funding. Without such a resource commitment, we run the risk of exacerbating an already tenuous relationship with HCFA and possibly having to back peddle from the registry.

There may be a benchmark we may wish to reach before making a final funding decision. The pacemaker registry regulations have been included in the Agency's 1985 regulation program which was developed in response to the new Executive Order authorizing OMB to approve significant regulation activities before they are initiated. Should OMB not endorse the pacemaker registry regulations, our efforts with HCFA and the need for additional resources become moot.

Because we have already passed the statutory deadline of January 1, 1985, we will continue to proceed with our planning activities related to the registry until and unless we cannot continue due to lack of funding or OMB approval. Should you desire any further information in connection with this matter, please let us know.

John C. Villforth

Attachments

cc: Mr. Meyer
Mr. Wetherell
Mr. Benson
Mr. Eccleston
Ms. Suydam/Ms. Lenahan
Mr. Britain/Mr. Rahmoeller
Mr. White/Dr. Andersen
Mr. Gundaker

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Memorandum

Date FEB 22 1985

From Director
Center for Devices and Radiological Health

Subject Cardiac Pacemaker Registry Legislation -- ACTION REQUESTED

To Director
Bureau of Eligibility, Reimbursement and Coverage
Health Care Financing Administration

I am writing in follow up to your January 23, 1985 memorandum to Mr. Robert Eccleston of my staff regarding the cardiac pacemaker registry provisions of the "Deficit Reduction Act of 1984." After a careful reading of your memo, we are somewhat concerned that it failed to fully reflect the agreements that were reached by staff of our two organizations.

Implementation Responsibilities

In a recent briefing on the pacemaker registry legislation by Mr. Eccleston and others, I was advised that during meetings with representatives of BERC and other HCFA components, there was considerable discussion about existing mechanisms through which the required data is or could be collected. It is my understanding that BERC staff suggested use of HCFA's intermediary network for collecting the information on pacemaker implants/explants and warranties. Under this scheme, FDA, in turn, will maintain the registry and provide the data analysis. This approach has two salutory effects: first, it builds on an already-established reporting scheme; and second, it reduces the Department's overall costs in administering the law.

I believe it is important to maintain the momentum that our staffs have established. To that end, I would like to suggest that an interagency task force, comprised of appropriate HCFA and FDA staff, be created to work out a formal working agreement and specific implementation details, many of which were touched on in your memo. Should you agree with this suggestion, I would ask that you designate 3-5 persons to represent HCFA in the areas of data collection, program operations, and regulations development. Please forward the names of your designees to Ms. Donna Lenahan of our Office of Management and Systems, whom we have assigned to oversee the next phase(s) of this project by February 28. We are now in the process of assembling our team, which will include staff from our regulations, compliance, and scientific staff. We will forward the names of our representatives to Mr. Frank Spruill or Ms. Sharon Hippler within the next week.

'85 FEB 26 PM 3 [illegible]
HCFA, OFC. [illegible]

Report to Congress

Reportedly, Congressional interest in this activity is likely to continue, particularly on the part of the Senate Special Committee on Aging. In view of this and the fact that the statutory deadline is now past, I would propose that we inform the Congress on the progress we have made thus far and on our future plans. This might best be accomplished by a letter-report to Senator Heinz, co-signed by appropriate officials of each of our agencies. As Mr. Eccleston indicated to Mr. Stan Katz in a recent telephone conversation, we are willing to take the lead in drafting such a report and then share it with you for review and sign-off. It would be helpful if your staff could provide us at the same time you submit your task force nominations with a written description of the data collection scheme HCFA is proposing to use, which we could incorporate into the report to Congress.

OMB Review of Registry Regulations

As I am sure you are aware, OMB is now authorized by virtue of Executive Order 12498 to review and approve or disapprove newly-planned regulations before formal action on them begins. I should note that in FDA's submission to the Department, the pacemaker registry regulations were included as an item for HHS and OMB review. So the possibility exists that the regulations needed to underpin the registry could be at risk of veto by OMB. This review notwithstanding, I believe we should proceed as planned.

We appreciate the efforts you and your staff have made to date, and we look forward to working out an effective implementation plan that will help us both fulfill our respective responsibilities under the law.

John C. Villforth

John C. Villforth

Medicare

Peer Review Organization Manual

INTERIM MANUAL INSTRUCTION

Department of Health and Human Services
Health Care Financing Administration

Transmittal No. IM 85 - 2

Date MARCH 1985

NEW MATERIAL	PAGE NO.	REPLACED PAGES
Table of Contents	(5 pp.)	----
Chapter 2 Sec. IM 2000 - IM 2070	(62 pp.)	----
Attachment A-1	(1 p.)	----

NEW PROCEDURES - EFFECTIVE DATE: MARCH 25, 1985

In accordance with the PRO contract, Article VIII - Technical Direction and Article IX - Conditions of Performance, PROs are required to comply with requirements as set forth in program instructions. The HCFA Program Issuance System provides instructions and guidelines on program matters.

This issuance does not apply to PPS-exempt States or territories (i.e., Guam, Puerto Rico, or Virgin Islands) or to States with approved waivers of the PPS system, (i.e., Maryland, Massachusetts, New Jersey or New York). There will be a separate issuance for these States and territories delineating applicable sections of the requirements contained in this issuance.

This issuance incorporates the review procedures for the required medical review activities of the PRO contracts. There have been revisions to the required review activities - some of which increase the level of review, while others decrease workload. The major changes are:

Revision	Section
Admission Review - Incorporated policy applying to noncovered admissions with a covered level of care rendered during the stay.	IM 2050.1A.4
Outlier Review - Reduced the level of review for day and cost outlier cases. Expanded the cost outlier review instructions to require PROs to review for fragmented charges during review of outlier services/items.	IM 2050.2

Procedure Review - Eliminated the requirement to collect pacemakers warranty information as the Food and Drug Administration now maintains a national registry on pacemakers.	IM 2050.3A
DRG Validation - Codified physician attestation policy (effective October 1, 1984) and monitoring requirements.	IM 2050.4A3
- Added section explaining physician requirements for physician attestation.	IM 2050.4A3a(3)
- Reduced DRG sample size for small hospitals.	Attachment A-1
- Revised policy on notifying hospitals of cases to be reviewed no more than 24 hours before onsite review. New policy requires notification 2 working days before onsite review.	IM 2050.4B5
- Added review of DRG adjustment bill which result in a higher-weighted DRG.	IM 2050.4E
Preadmission/Preprocedure Review - Explains the preadmission/preprocedure review and verification requirements.	IM 2050.5
Review for Noncovered Items/Services - Codified requirements for review for noncovered items/services during course of PRO reviews and of cases referred by fiscal intermediaries for medical necessity determinations.	IM 2060
Record of Review Activities - Outlines documentation and retention of record requirements.	IM 2070

The above summary outlines only major revisions. The attached section contains many clarifications and explanations of the review procedures in response to comments from PROs and other organizations. This revision should therefore be reviewed in its entirety.

Workload and Cost

The attached transmittal does affect the level of effort and cost required under the contract. The net result of these changes is estimated to be a 5% reduction in total workload/cost over the remainder of the contract period.

We do, however, recognize that the impact of this transmittal may vary in individual areas.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

DCP

Memorandum

Date MAR 15 1985

From Director
Center for Devices and Radiological Health

Subject CDRH Implementation of Cardiac Pacemaker Registry - INFORMATION

To The Commissioner
Through: Exec Sec ______

At one of our last one-on-one meetings, Jim Benson and I mentioned OMB's recent decision to disapprove the Agency's funding requests to support the cardiac pacemaker registry activities. You asked that we provide you with background information on what the pacemaker registry legislation requires of us, and when and what level of resources are needed to carry out this new mandate. Let me begin by recapitulating the facts.

Background on the Registry

The law basically requires the following actions:

- FDA must establish a national registry to serve as a repository for certain pacemaker and pacer lead implant/explant and warranty information. Submission of this information by physicians and providers, which relates only to Medicare pacemaker procedures (about 80% of those performed in the U.S.), would be a condition for Federal reimbursement.

- Explanted pacemakers and leads may be required to be returned to the manufacturer for testing which, again, could be linked to Medicare reimbursement. FDA is also authorized to participate in such testing on a discretionary basis.

- FDA must develop regulations to carry out the above activities. Promulgation of regulations, for which FDA will have lead responsibility with input from the Health Care Financing Administration (HCFA), will be in two stages. In the first stage regulation(s) to establish the registry will be developed. These regulations will detail what data are to be submitted, describe how the data will be used by FDA and HCFA, etc. The regulations will also serve as a notice of intent to develop — during the second stage — a proposed rule on the return of explanted pacemakers and leads to manufacturers and on the testing of the explanted devices by manufacturers.

Because of the obvious linkage between this law and Medicare reimbursement activities, we are coordinating our activities with HCFA in the areas of regulations development and data collection (see memoranda at Tab A).

Registry Funding

During our discussion, you asked that we provide you with a chart which illustrates our legislative implementation strategy and resource estimates at the various stages. Provided at Tab B is such a chart, which indicates the need for 11 FTE's and $1.2 million annually to fully initiate and operate the pacemaker registry. Also at Tab B is another chart which depicts the implementation strategy devised by a Center taskforce. In view of the fact that we are presently soliciting commitments from HCFA and the fact that we will soon need to issue a request for proposals from outside contractors for operation of the registry and analysis of the data base, I believe it is necessary to have the requisite resources available up front.

Notwithstanding your recent offer to re-direct 5 staff-years from your immediate Office to the Center in support of this activity, we will still suffer a net loss of resources after the cuts planned for FY 86 take effect. Thus, implementation of the registry legislation will require some compromise in our other statutory responsibilities in the device area.

OMB Review of Registry Regulations

There is yet another issue that may bear in this activity. As you know, the pacemaker registry regulations were included in the Agency's 1985 regulation program which was developed in response to Executive Order 12498 authorizing OMB to approve significant regulatory activities before they are initiated. Should OMB not endorse the pacemaker registry regulations, our efforts with HCFA and the need for additional resources become moot. But because we have already passed the statutory deadline of January 1, 1985, we will continue to proceed with our activities in this area until and unless we cannot continue due to lack of additional funding or OMB approval.

Should you desire any further information in connection with this matter, please let us know.

John C. Villforth

Attachments (Tabs A & B)

[Please see above appendix items for following memoranda:

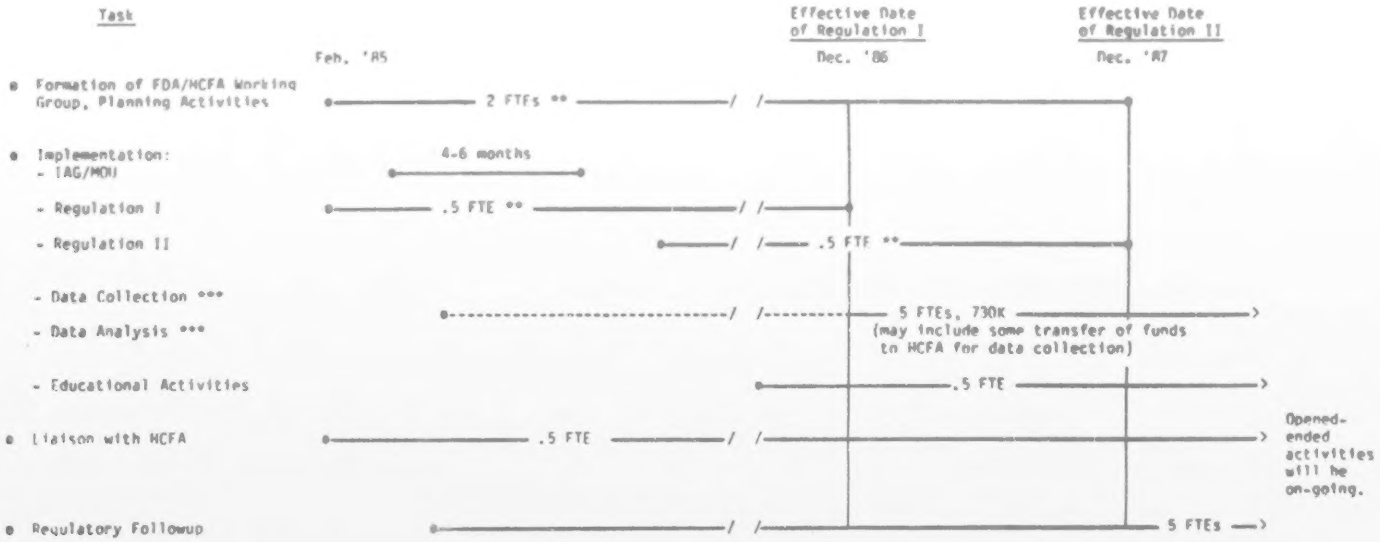
January 23, 1985 memorandum from the Director, Bureau of Eligibility, Reimbursement, and Coverage, HCFA, to Mr. Robert C. Eccleston, FDA

and

February 22, 1985 memorandum from Director, Center for Devices and Radiological Health, FDA, to Director, Bureau of Eligibility, Reimbursement, and Coverage, HCFA.]

56-653 O--86----16

Implementation Costs of Pacemaker Registry *



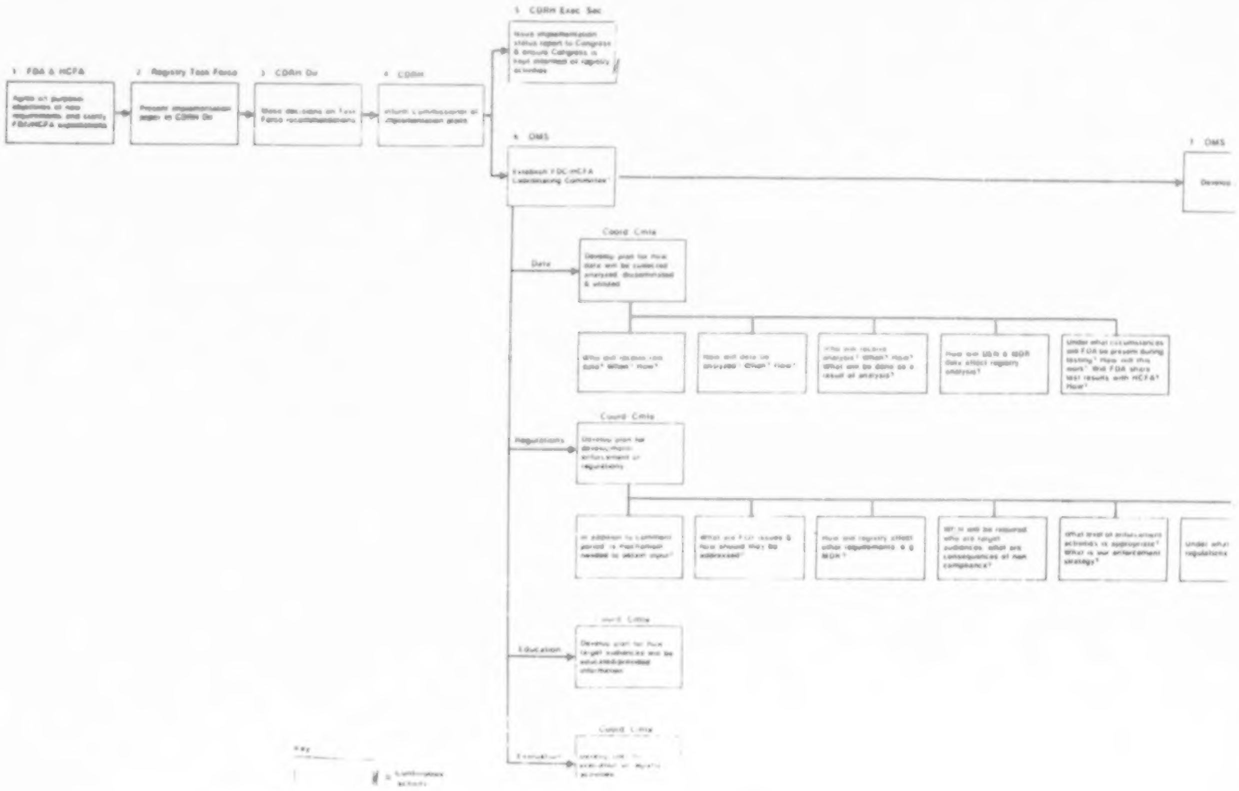
Annual costs associated with pacemaker registry estimated to be 11 FTEs, $1,170K (dollar figure includes salaries at 40K per FTE).

* FTEs include overhead.

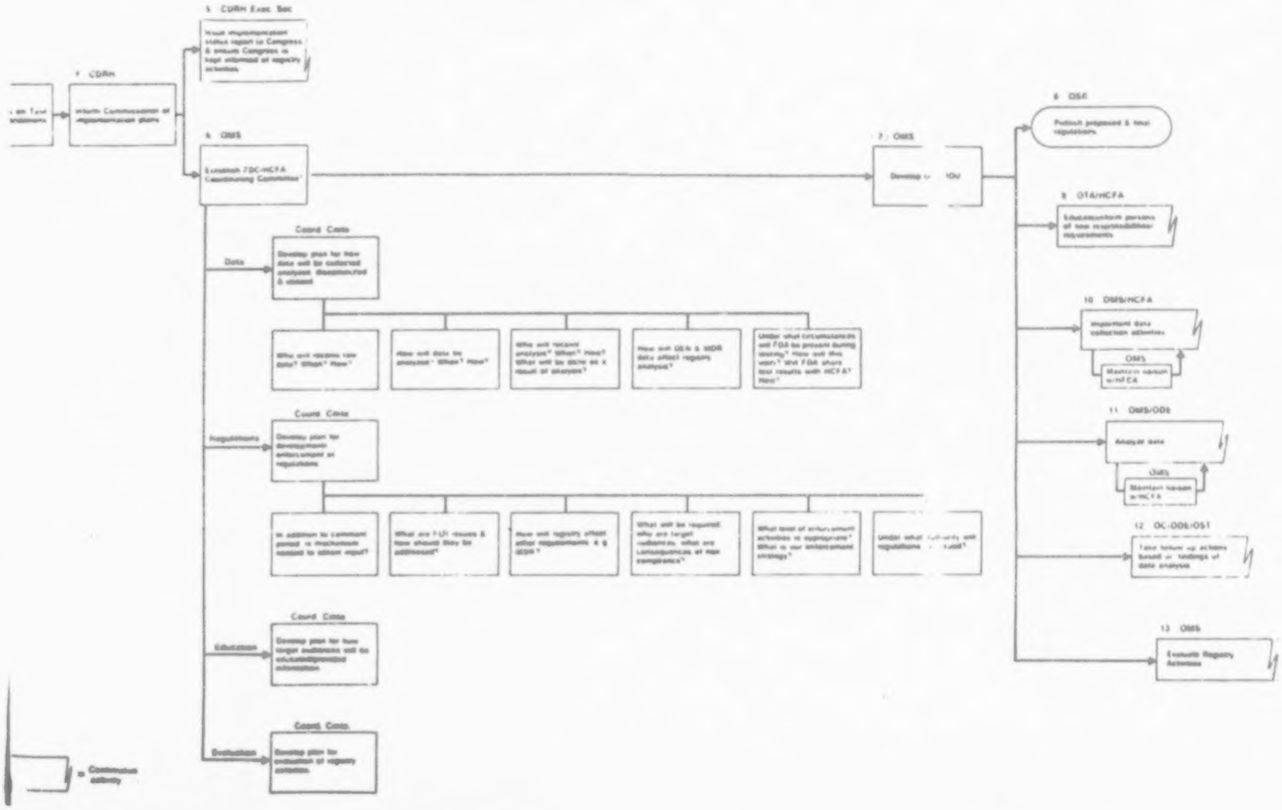
** A one-time expense.

*** Dotted line indicates collection and analysis of pilot data.

Basic Implementation Strategy for Cardiac Pacemaker Registry


1 FDA & HCFA
Agree on purpose, objectives of new requirements, and clarify FDA/HCFA expectations
2 Registry Task Force
Present implementation plan to CDRH Dir
3 CDRH Dir
Make decisions on Task Force recommendations
4 CDRH
Inform Commissioner of implementation plans
5 CDRH Exec Sec
Issue implementation status report to Congress & ensure Congress is kept informed of registry activities
6 OMS
Establish FDA-HCFA Coordinating Committee
7 OMS
Develop
Data
Coord Cmte
Develop plan for how data will be collected, analyzed, disseminated & utilized
Who will collect the data? When? How?
How will data be analyzed? When? How?
Who will receive analysis? When? How? What will be done as a result of analysis?
How will USR & MDR data affect registry analysis?
Under what circumstances will FDA be present during testing? How will this work? Will FDA share test results with HCFA? How?
Regulations
Coord Cmte
Develop plan for development, enforcement of regulations
In addition to comment period is mechanism needed to obtain input?
What are FOI issues & how should they be addressed?
How will registry affect other requirements, e.g. MDR?
Who will be required; who are target audiences; what are consequences of non compliance?
What level of enforcement activities is appropriate? What is our enforcement strategy?
Under what regulations
Education
Coord Cmte
Develop plan for how target audiences will be educated/provided information
Evaluation
Coord Cmte
Develop plan for evaluation of registry activities
Key
= Continuous action

Basic Implementation Strategy for Cardiac Pacemaker Registry


4 CDRH
Inform Commissioner of implementation plans
5 CDRH Exec. Sec
Issue implementation status report to Congress & ensure Congress is kept informed of registry activities
6 OMS
Establish FDC-HCFA Coordinating Committee
Data
Coord. Cmte
Develop plan for how data will be collected, analyzed, disseminated & utilized
Who will receive raw data? When? How?
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How will DEN & MDR data affect registry analyses?
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Regulations
Coord. Cmte
Develop plan for development, enforcement of regulations
In addition to comment period, is mechanism needed to obtain input?
What are FDA issues & how should they be addressed?
How will registry affect other requirements, e.g. IDE?
What will be required, who are target audiences, what are consequences of non compliance?
What level of enforcement activities is appropriate? What is our enforcement strategy?
Under what authority will regulations issued?
Education
Coord. Cmte
Develop plan for how target audiences will be educated/provided information
Evaluation
Coord. Cmte
Develop plan for evaluation of registry activities
7 OMS
Develop MOU
8 OSR
Publish proposed & final regulations
9 OTA/HCFA
Educate/inform persons of new responsibilities/requirements
10 OMS/HCFA
Implement data collection activities
OMS
Maintain liaison w/HCFA
11 OMS/ODE
Analyze data
OMS
Maintain liaison w/HCFA
12 OC/ODE/OST
Take follow up actions based on findings of data analysis
13 OMS
Evaluate Registry Activities
= Continuous activity

CARDIAC PACEMAKER REGISTRY

- The cardiac pacemaker registry requirements of the recently enacted Deficit Reduction Act of 1984 would have a number of cost implications for FDA. These estimates are based on the requirement that FDA monitor and assist manufacturers in the testing of pacemakers and leads. Previous versions of this legislation would have required FDA to conduct testing.

- These estimates reflect annual costs. It should be noted that, while costs associated with promulgating regulations are one-time costs, roughly the same level of effort would be required, once these regulations are in place, for increased monitoring and compliance activity in subsequent years. We are assuming that 120,000 pacemaker/lead implants/replacements will be entered into the registry per year and that the devices currently implanted in patients prior to the effective date of the new law will not be registered.

DETAIL OF COST ESTIMATES

	FTE	CONTRACT	TOTAL $000
Regulatory development, implementation and compliance monitoring & follow-up (regulation development in the first year will be replaced by increased monitoring in subsequent years)	5		200
Automated Registry System	1	730	770
Report Review	2		80
Device Testing Assistance	3 1/		150
	11	730	1,200

1/ FTEs associated with device testing assistance are calculated at $50,000; all others are $40,000.

Revised
10/11/84

CONTACT REPORT
(Use Ink or Typewriter)

CONTACT: Donna Lenahan
ORGANIZATION: FDA
PHONE: 112-443-5807
DATE: 3/22
TIME:
☑ PHONE
☐ PERSONAL

SUBJECT: Pacemaker Registry Task Force

(Check applicable box)
☐ CONTRACT FILE
☐ INTERMEDIARY FILE
☑ OTHER (Specify) RN PM Registry

COPIES ROUTED TO
R. Milhorn
MLM
S. Katz
J. Case
M. French
F. Sprowl

RESUME

Donna called re: the agenda for the first meeting of the Pacemaker Registry Task Force. She has tentatively targeted the following as discussion topics: Introduction (individual areas of responsibility), status of reg. development, presentation and discussion of Draft Report to Congress (Progress report to Heinz), CPO's data collection form & data collection strategy, development of memo of understanding & unresolved issues (each Agency's use of data, concern re: testing and return of devices

Donna will send a copy of the proposed agenda ASAP. She has tentatively suggested April 4th a date of first meeting.

ACTIONS REQUIRED

PREPARED BY: Sharon E. Hippler
PHONE EXTENSION: 48564
ORGANIZATION DESIGNATION: DMSCP
BUILDING AND ROOM NO.: 457-EHR
FOLLOW-UP DATE:
PAGE 1 OF 1

FORM SSA-1773 (3-70)

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Memorandum

Date MAR 29 1985

From Program Analyst, Division of Planning and Evaluation,
Office of Management and Systems, CDRH (HFZ-30)

Subject First Meeting

Jim Case

To Members, FDA/HCFA Pacemaker Registry Working Group

I have been designated to coordinate the establishment of a pacemaker registry, as specified in section 2304, "Pacemaker Reimbursement, Review and Reform", of the Deficit Reduction Act of 1984, within the Center for Devices and Radiological Health (CDRH), Food and Drug Administration (FDA). Your names have been submitted to me by CDRH Office Directors and Ms. Sharon Hippler, of the Bureau of Eligibility, Reimbursement, and Coverage (BERC), Health Care Financing Administration (HCFA), as representatives of your organizations to a joint FDA/HCFA the Pacemaker Registry Working Group. The formation of this group was suggested by CDRH Director John Villforth to work out a formal agreement and specific details for implementing the registry. Your contribution to the development of the registry in the months to come is vital to its success and the effort, I think, will be a valuable experience for us all. Tab A contains a list of working group members, mailing addresses, and phone numbers.

First, let me summarize the requirements of section 2304 of the Deficit Reduction Act of 1984 as it pertains to the establishment of a pacemaker registry.

- FDA shall by regulation provide for a registry of all cardiac pacemaker devices for which payment was made under Medicare. The registry shall include the manufacturer, model number, and serial number of the device(s); the names of the device recipient and the physician performing the procedure; the date and location of the procedure; the name of the provider billing for the procedure; any expressed or implied warranties associated with the device(s); and any other information deemed appropriate.

- The registry has four purposes: 1) to assist the Secretary in determining when payments may properly be made under Medicare; 2) in tracing the performance of the devices; 3) in determining when inspection of the devices by manufacturers may be necessary; and 4) in carrying out studies with respect to the use of the devices.

The legislation provides for, but does not require,:

- o the return by providers of explanted devices to manufacturers for testing;
- o the provision of the results of such testing to providers along with information about any the warranties for the device;
- o the presence of FDA personnel at such device testing; and
- o the denial of Medicare payment, in whole or part, if the requirements of the legislation are not complied with.

Tab B contains a copy of this legislation and a flowchart of the requirements and decision steps which apply to FDA in implementing this legislation. The flowchart was developed as an internal CDRH analytical tool and does not address HCFA's decision processes.

Since the Deficit Reduction Act was signed last summer, there have been two meetings between CDRH and HCFA staff to discuss the roles and expectations of each organization in implementing the registry. There was considerable discussion of existing mechanisms through which the registry data could be collected. BERC staff suggested use of HCFA's intermediary network for collecting the data. In turn, CDRH offered to maintain the registry and provide data analysis. Tab C contains a draft data collection form sent to me by Frank Spruill, Bureau of Program Operations, HCFA, for comment. Please look this over, keeping in mind the objectives the registry is supposed to fulfill and the requsite data elements. Discuss it with appropriate individuals within your organizations and be prepared to critique it at our first meeting.

Formal communication between the Directors of CDRH and BERC have been initiated. Your nominations to this working group are a direct result of this. Tab D contains two communiques to let you know the extent of formal communications between our two organizations.

Tab E contains a flowchart of CDRH's registry implementation strategy. Again, this flowchart may not fully represent all that HCFA must consider in implementing the registry, but it gived HCFA representatives to the working group an idea as to where CDRH need to go with this.

Step five in the flowchart refers to development of a status report to Senator Heinz on our progress in implementing the registry. Robert Eccleston, CDRH's Associate Director for Intergovernmental Liaison, proposed drafting such a report to be co-signed by FDA Commissioner Young and HFCA Administrator Davis (see page 2 of memo of February 22 at Tab D). Tab F contains this draft report. Please consider the following questions for discussion at our first meeting:

- Does the report accurately reflect the agreements that have been reached thus far between our two organizations?
- How much detail can/should the report go into regarding the data collection scheme at this point?
- Should anything be added to or deleted from the report?
- Should we proceed with this report voluntarily, or wait until it is requested by the Senate Special Committee on Aging?

Currently, we are at step six of our implementation flowchart, the formation of the working group, (coordinating committee). We need to begin laying the groundwork for regulations development, data collection and analysis, return and testing of explanted devices, and regulatory followup. Steps seven through 11 represent the activation of the registry activities and will progress with the deliberations of this committee.

At Tab G is an agenda for our first meeting, to be held at 9 am on Friday, April 5, in room T-400, Building Four, Twinbrook Complex, 12720 Twinbrook Parkway, Rockville, Maryland. Also at Tab G is a map to direct you. Because of the distance between CDRH and HCFA, I will try to alternate meeting locations between Rockville and Baltimore. I will also try to keep the number of meetings to a minimum. However, to do this, the meetings we do have must be as productive as possible. Please attend meetings and come prepared to discuss agenda items. If you absolutely cannot attend a meeting, send an informed alternate.

If anyone has additional agenda items for our first meeting, please let me know as soon as possible and I will include them on the agenda.

I look forward to meeting and working with each of you in this effort.

Donna M Lenahan

Donna Lenahan

Attachments

cc: Suydam

CDRH/HCFA Pacemaker Registry Working Group Members

CDRH Members

Donna Lenahan
Acting Chief, Planning Branch
Division of Planning, Evaluation
and Information Services
Office of Management and Systems
5600 Fishers Lane (HFZ-30)
Rockville, Maryland 20857
FTS 443-5807

Glen Rahmoeller, Director
Division of Cardiovascular Devices
Office of Device Evaluation
8757 Georgia Avenue (HFZ-450)
Silver Spring, Maryland 20910
FTS 427-7594

Fred Hooten
Chief, Manufacturing and
and Quality Assurance Branch
Division of Compliance Programs
Office of Compliance
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Silver Spring, Maryland 20910
FTS 427-7194

Robert Skufca, D.O.
Medical Officer
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Wendy Johnson
Health Science Administrator
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William Dierkshiede, Ph.D.
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Rockville, Maryland 20857
FTS 443-2845

Mel Altman, Ph.D.
Director, Planning Staff
Office of Standards
and Regulations
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Bureau of Eligibility,
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Jim Case
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Bill Rush
Regulations Staff
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Sharon Hippler
Office of Coverage Policy
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FTS 934-8564

Michelle French
Regulations Staff
Bureau of Eligibility,
Reimbursement and Coverage
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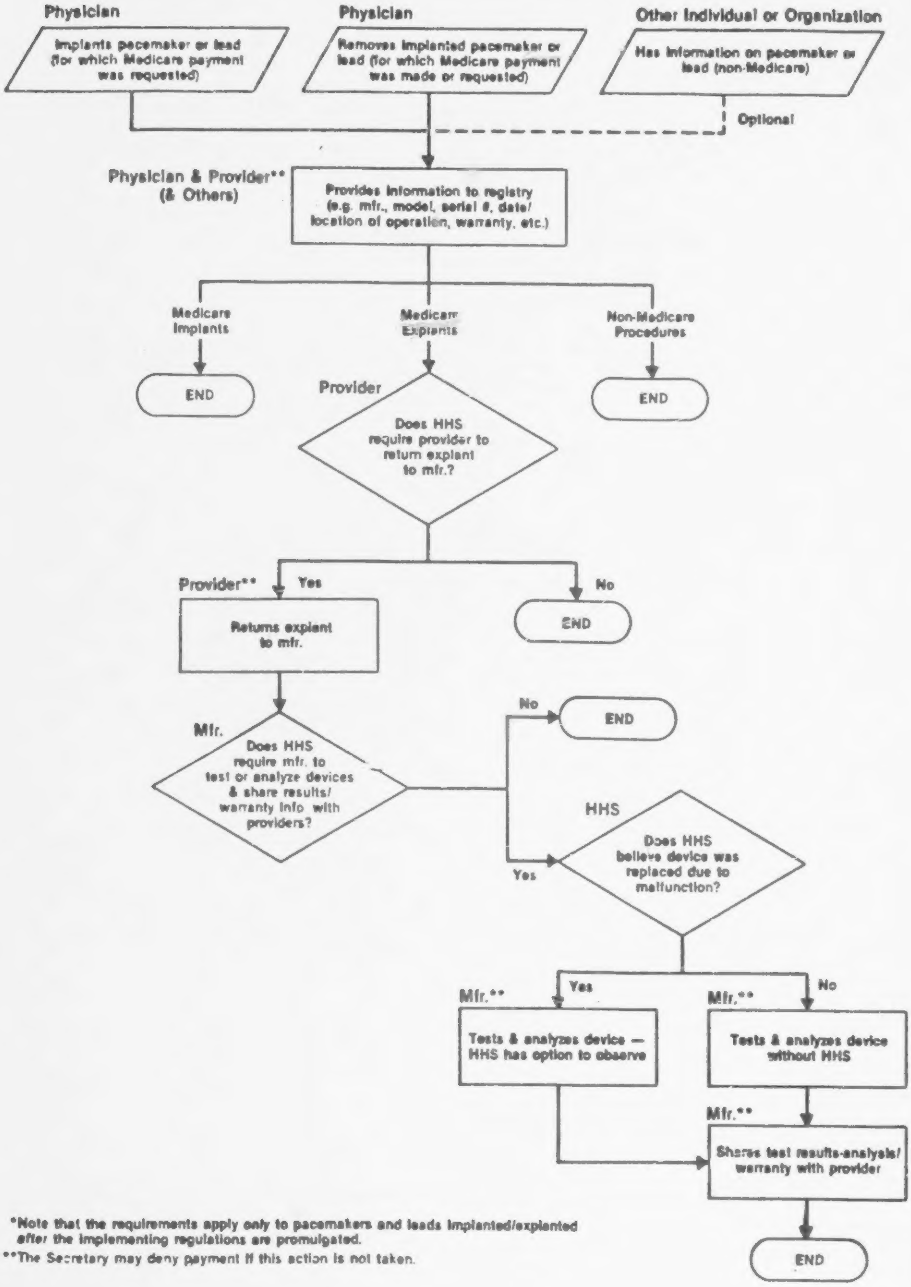
5325 Security Boulevard
Baltimore, Maryland 21207
FTS 934-5610

[Please see Appendix Item Entitled "Pacemaker Provisions of Deficit Reduction Act of 1984", above.]

Flow Chart of Pacemaker Registry Legislation Requirements*


Physician
Implants pacemaker or lead (for which Medicare payment was requested)
Physician
Removes implanted pacemaker or lead (for which Medicare payment was made or requested)
Other Individual or Organization
Has information on pacemaker or lead (non-Medicare)
Optional
Physician & Provider** (& Others)
Provides information to registry (e.g. mfr., model, serial #, date/location of operation, warranty, etc.)
Medicare Implants
Medicare Explants
Non-Medicare Procedures
END
END
Provider
Does HHS require provider to return explant to mfr.?
Provider**
Yes
No
END
Returns explant to mfr.
Mfr.
Does HHS require mfr. to test or analyze devices & share results/warranty info with providers?
No
END
HHS
Yes
Does HHS believe device was replaced due to malfunction?
Mfr.**
Yes
Mfr.**
No
Tests & analyzes device — HHS has option to observe
Tests & analyzes device without HHS
Mfr.**
Shares test results-analysis/warranty with provider
END

*Note that the requirements apply only to pacemakers and leads implanted/explanted after the implementing regulations are promulgated.

**The Secretary may deny payment if this action is not taken.

Name of Hospital
Hospital
Address

1. Patient: Date:
2. HIC ____________
3. Dates of Confinement ____________

The medical information on the claim you recently submitted for the above confinement indicates pacemaker related services. Section 2304 of P.L. 98-369 requires that we obtain from you the information listed below for inclusion in the Food and Drug Administration's Pacemaker Registry. Your response to this request within 30 days of the date of this letter is appreciated.

Identification number of physician performing the pacemaker related procedure: 4. ____________

Identification number of physician ordering the pacemaker related procedure: 5. ____________

Date of pacemaker-related procedure implant: 6. ____________

Pacemaker information:

	Component	Mfgr	Model	Serial Number
a.	Pulse Generator	7)	8)	9)
b.	Atrial Lead	10)	11)	12)
c.	Ventricular Lead	13)	14)	15)
d.	Bipolar Lead	16)	17)	18)

If this patient previously had a pulse generator, which was explanted during this stay provide the following:

If available provide:

Date of pacemaker explant 19) ____________

	Component	Mfgr	Model	Serial Number
e.	Explanted Pulse Generator	20)	20)	22)

[Please see above appendix items for following memoranda:

January 23, 1985 memorandum from the Director, Bureau of Eligibility, Reimbursement, and Coverage, HCFA, to Mr. Robert C. Eccleston, FDA

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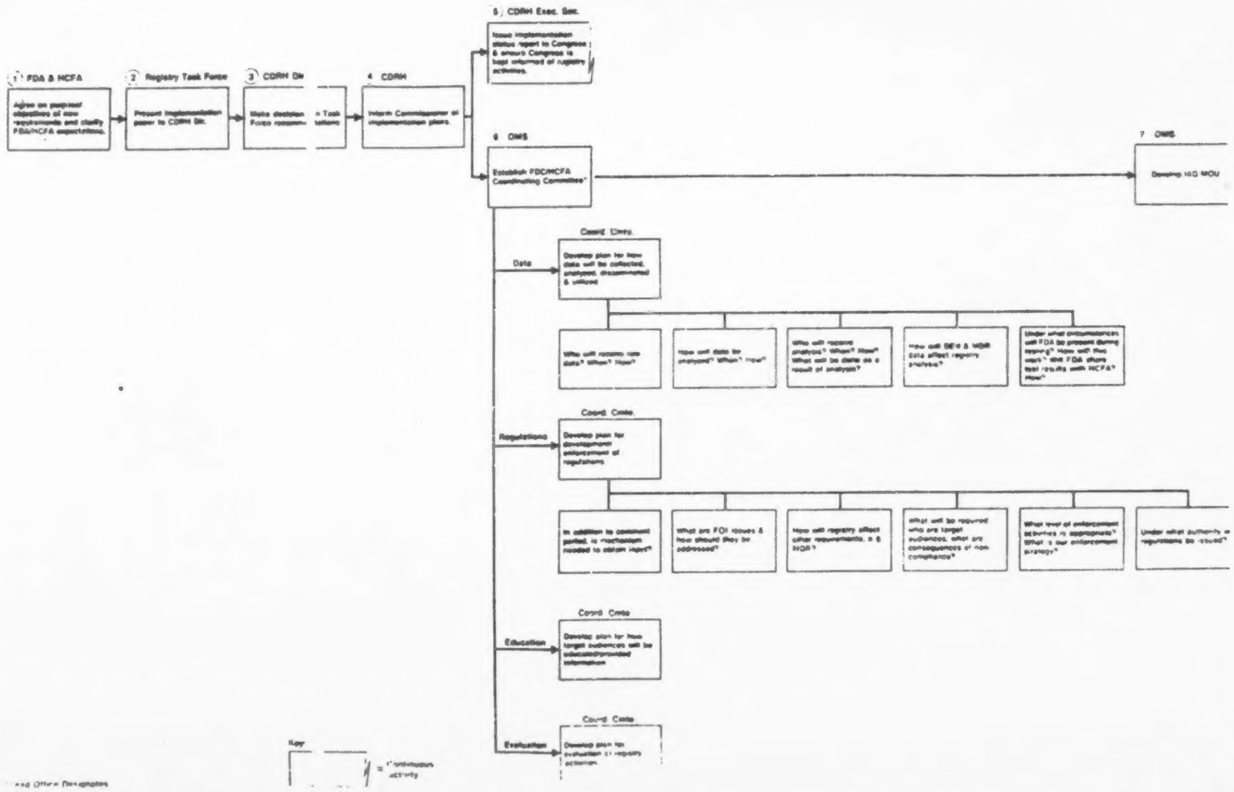
February 22, 1985 memorandum from Director, Center for Devices and Radiological Health, FDA, to Director, Bureau of Eligibility, Reimbursement, and Coverage, HCFA.]

Basic Implementation Strategy for Cardiac Pacemaker Registry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Make decision n Task Force recomm tions
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Inform Commissioner of implementation plans.
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Issue implementation status report to Congress & ensure Congress is kept informed of registry activities.
6 OMS
Establish FDA/HCFA Coordinating Committee*
7 OMS
Develop IAG MOU
Data
Coord. Cmte.
Develop plan for how data will be collected, analyzed, disseminated & utilized
Who will receive raw data? When? How?
How will data be analyzed? When? How?
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What level of enforcement activities is appropriate? What is our enforcement strategy?
Under what authority w regulations be issued?
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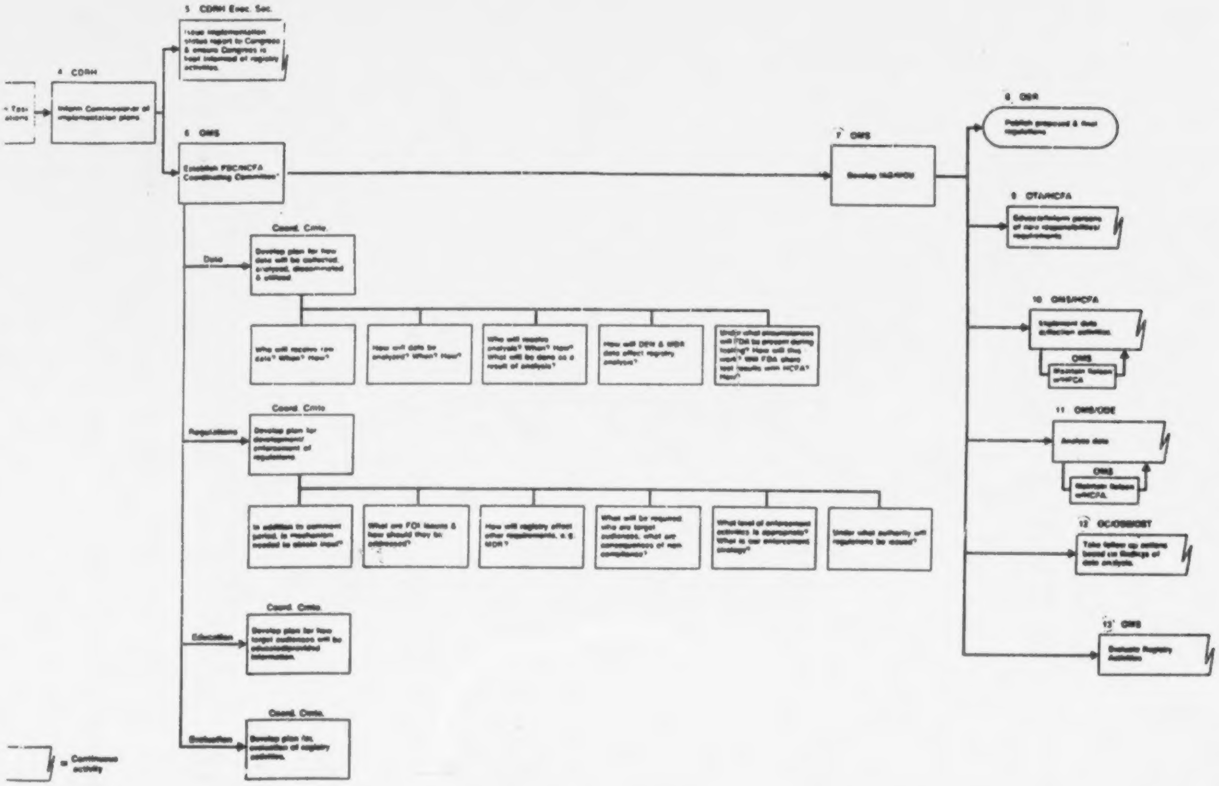
Evaluation
Coord. Cmte.
Develop plan for evaluation of registry activities
Key
= Continuous activity
Lead Office Designation

Basic Implementation Strategy for Cardiac Pacemaker Registry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Analyze data
OMS
Maintain liaison w/HCFA.
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Take follow up actions based on findings of data analysis.
13 OMS
Evaluate Registry Activities
= Continuous activity

The Honorable John Heinz
Chairman
Senate Special Committee on Aging
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

Shortly after passage of the Deficit Reduction Act of 1984 (P.L. 98-369), which contained provisions relating to establishment of a nationwide cardiac pacemaker registry by the Food and Drug Administration (FDA), several Departmental staff met with members of your Committee staff to discuss the requirements of the new law and underlying Congressional intent. At that session, we were reminded of your continuing interest in this issue and were asked to keep you apprised of our progress as we move forward in implementing the legislation. This letter report, then, is intended as an update on the steps we have taken to date ~~thus far~~ and what actions lie ahead. We would also like to share with you our basic perspectives about the law which have guided our actions thus far. ~~to date.~~

Based upon your 1982 Committee report, "Fraud, Waste, and Abuse in the Pacemaker Industry," and the evolution of the legislation noted above, it became clearly evident to us that the primary goal was to curb excessive and unnecessary payments under Medicare for pacemakers ~~pacemakers~~ and pacer lead implant/explant procedures. This is particularly true for those implant procedures involving a device which is still under warranty and/or the subject of an FDA product recall. An important, yet peripheral objective is to provide a mechanism for monitoring and evaluating the long-term performance of pacemakers and leads in order to more quickly pinpoint generic failures or defects as they occur. As envisaged by the Congress, this information, along with notification of FDA recalls that result from product malfunctions identified by the registry, would be made available and factored into the Department's reimbursement decision-~~decision~~-making process.

Because of the cost containment thrust of the legislation, it was imperative that the FDA and the Health Care Financing Administration (HCFA) begin discussions on the roles and responsibilities of each agency and the ways in which we can collaborate. These talks, which began last year, have been productive and we are pleased to report that a conceptual implementation scheme has been devised and efforts are now underway to develop a specific interagency working plan. We would like to outline some of the key elements of the plan and provide an overall timetable. Obviously, full implementation of the plan will take us beyond the January 1, 1985 deadline established by the law which, as was noted in our meeting with your staff, is one that simply could not be met.

One of the main provisions of the law calls for the submission of certain information concerning pacemaker implants and explants and related warranties by "providers" to the FDA-based registry. It occurred to us that much of this information is already being collected as a part of the Medicare reimbursement process.

To avoid re-inventing the wheel, we plan to require implanting physicians and providers to report the statutorily-prescribed information to HCFA through its intermediary network.

Once collected by HCFA, the data would be shared with the FDA, which will serve as the custodian of the registry. At this point, we favor the idea of contracting for the establishment and operation of the registry, along with the conduct of actuarial analyses to identify generic device problems. A number of computer management firms, some specializing in cardiac pacemakers and leads, have brought their interests and capabilities to our attention, and we will be considering these and perhaps other organizations in the coming months.

On the issue of regulations, FDA will have lead responsibiity, again with input from HCFA. Promulgation of the rules will be done in two stages. In the first stage, the regulations will delineate what information is required under the FDA-managed registry and when it must be submitted, in addition to specifying how the data will be used by both agencies. In the second stage, we intend to propose rules on the return of explanted pacemakers and leads to manufacturers, the testing of failed devices by manufacturers and sharing of test results with providers, and the circumstances under which FDA staff will participate in product testing.

Our regulatory plans are presently being reviewed by the Department and the Office of Management and Budget in accordance with Executive Order 12498 which the President issued on January 4 of this year, and which requires the submission of a regulatory program by agencies in the Executive Branch. This activity, which applies to significant regulatory actions (like the pacemaker registry), is designed to ensure that the development of major regulations is necessary from a cost-benefit standpoint, that such initiatives are not duplicative or in conflict with other regulatory efforts, and that they conform to the Administration's overall goals and policies. We expect to receive word from OMB and the Department on our proposed pacemaker registry regulations by next month. We anticipate issu~~ed~~ing regulatory proposals by September 1985.

To accomplish the above and in an effort to coordinate the regulations development and other actions related to this legislation by our respective agencies, we have formed an~~d~~ interagency task force. This working group has been charged to handle the details necessary to make the registry operational, to develop policies on data collection and analysis, ~~that dovetail with other~~ and to jointly develop implementing regulations that will enable both agencies to carry out their functions in a compatible and effective way.

I should note that as part of our efforts to design the registry and develop testing and analysis procedures, we have solicited views from groups outside the government. In particular, we have discussed the proposed registry with a number of pacemaker manufacturers, which have formed a group under the aegis of the Health Industry Manufacturers Association. We also plan to consult other groups such as the American College of Cardiology, the private American Society for Pacing and Electrophysiology, among others.

We believe that a good start has been made in carrying out the cardiac pacemaker registry provisions of the 1984 Deficit Reduction Act. The planning and design that has gone into this effort thus far should help to assure a viable and effective reporting system, one that will allow greater attention to be drawn to defective pacemakers and leads, and thereby enable us to make informed reimbursement decisions and to curtail unnecessary Federal expenditures.

We hope this overview is useful, and demonstrates our mutual commitment to implementing this law in a rational and effective manner.

Sincerely yours,

Frank E. Young, M.D., Ph.D.
Commissioner of Food and Drugs
Food and Drug Administration

Carolyne Davis, Ph.D.
Administrator
Health Care Finincing
Adminstration

Prepared by:RCEccleston:ss:3/11/85
Revised by:RCEccleston:3/12/85

FDA/HCFA Pacemaker Registry Working Group

Meeting I

Agenda

o Introductions, including

- your organization
- your role in implementing the registry
- your organization's involvement with the registry
- status report of registry-related activities/interest

o Status of regulations development (Mel Altman/Michelle French), including

- status of OMB review
- explanation of two-staged approach
- authority under which the regulations will be promulgated
- summary of CDRH/HIMA meeting on registry and regulations
- other avenues/audiences for obtaining public input, e.g., consumer groups, professional societies, etc.

o Report to Congress (Donna Lenahan)

- See page 3 of memo for specifics

o Data collection form (Donna Lenahan, Jim Case)

- elements
- format

o Data collection strategy (Jim Case)

- How will the data be collected?
- What steps have been taken to accomplish this?
- Is the plan to collect pilot data while promulgating the regulations still viable?
- Has HCFA received any feedback from those who would be collecting the data?

o IAG/MOU (Donna Lenahan, Sharon Hippler)

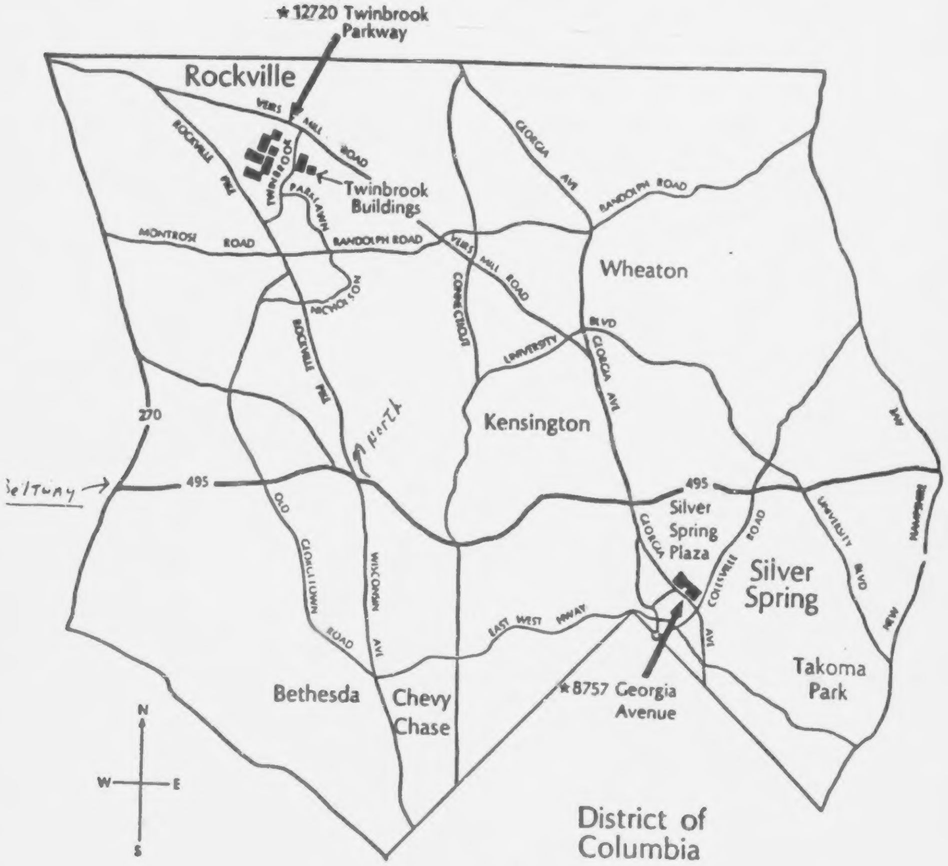
- focal point or contact person for development
- clearances

- Unresolved issues

  - How does each Agency plan to utilize the registry? How will the information fit into their decision-making processes?
  - What will each Agency's data analysis requirements be?
  - What are each Agency's criteria/concerns regarding the return of explanted devices?
  - What are each Agency's criteria/concerns regarding testing of returned devices?
  - How does each Agency plan to use the test results?
  - What will be each Agency's enforcement strategy in the event of:

    1) non-compliance with some aspect of the regulations, and
    2) a confirmed device performance problem?
  - What educational initiatives will need to be undertaken to inform manufacturers and providers of their new responsibilities?

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
Rockville - Silver Spring Area Map


★ 12720 Twinbrook Parkway
Rockville
VEIRS MILL ROAD
ROCKVILLE PIKE
TWINBROOK
PARKLAWN
Twinbrook Buildings
MONTROSE ROAD
RANDOLPH ROAD
NICHOLSON
GEORGIA AVE
RANDOLPH ROAD
VEIRS MILL ROAD
CONNECTICUT
Wheaton
BLVD
UNIVERSITY
GEORGIA AVE
ROCKVILLE PIKE
north
270
Kensington
Beltway
495
495
OLD GEORGETOWN ROAD
WISCONSIN AVE
Silver Spring Plaza
GEORGIA AVE
COLESVILLE ROAD
UNIVERSITY BLVD
NEW HAMPSHIRE AVE
Silver Spring
EAST WEST HWAY
★ 8757 Georgia Avenue
Takoma Park
Bethesda
Chevy Chase
N
W
E
S
District of Columbia

☆ U.S. GOVERNMENT PRINTING OFFICE: 1984-421-177

Pacemaker Registry
Outline of Proposed Rule Preamble

A. Statutory Requirements
    Deficit Reduction Act of 1984
    Social Security Act
    Food, Drug, & Cosmetic Act

B. Legislative History

C. The January 1, 1985 Deadline

D. Discussion of Pacemaker & Pacemaker Leads

E. Estimates of number of implantations and replacements that will be reported

F. How HCFA currently reimburses for pacemaker implants

G. HCFA's current pacemaker activities. (Medtronic lead issue PRO Review of claims for pacemaker implants)

H. Previous pacemaker registries

I. Purpose of Regulations

J. Two stages of regulations
    mandatory
    discretionary

K. Related regulations

L. Implementation
    1. Schedule

  2. Options discussed
  3. HCFA/FDA interagency work groups
  4. HCFA/FDA roles

M. The Registry Itself
  1. How to be established
  2. goals
  3. how maintained
  4. contract/in-house

N. Submission of Data
  1. What data will be submitted
     .required by legislation
     .additional data
  2. How to submit the information to registry (forms, frequency, etc, who submits, etc.)
  3. Non-Medicare pacemakers - how reported

O. Outputs
  1. Studies, Data Summaries & Reports
  2. Actuarial analyses to be done
  3. How data is to be used.
     - by HCFA
     - by FDA

P. Funding

Q. Implementation of Discretionary portions of Legislation/Notice of Intent
  1. Denial of Medicare claims
  2. Return of explanted devices or leads for testing
  3. Manufacturer testing & sharing results & warranty information with providers
  4. FDA observation of testing

R. Tracing Performance of Pacemakers and leads

S. Impact/Interrelationship with DEN, MDR, & GMP

T. Educational Initatives

U. Access of medical profession & others to registry
FOI & Privacy Act

V. OMB Review (E.O. 12498) of Regulations

W. Definitions

X. The Proposed Rule Itself

LWeinstein:rdh:4/2/85

SCHEDULE FOR PROCESSING JOINT FDA/HCFA PROPOSED REGULATION FOR PACEMAKER REGISTRY

April 4, 1985

ACTION STEPS	JOINT DATES	FDA DATES	HCFA DATES
HCFA circulation draft to OCP/HCFA			04/02/85
OCP/HCFA clearance of HCFA circulation draft			04/09/85
HCFA circulation draft to BERC Director (HCFA)			04/10/85
BERC Director (HCFA) clearance of HCFA circulation draft			04/12/85
HCFA circulation draft to AAP/HCFA			04/15/85
HCFA interim draft to CDRH/FDA--FYI only	04/15/85		
CDRH/FDA begins developing preliminary combined draft		04/16/85	
AAP/HCFA clearance of HCFA circulation draft			04/30/85
HCFA circulation draft to FDA	04/30/85		
Revise preliminary draft/circulate for comment to CDRH/FDA		05/07/85	
FDA combined draft to RS/HCFA for comment	05/17/85		
Combined draft to HCFA for circulation			06/01/85
Final CDRH/FDA sign-off/request ACRA and GC (FDA) review		06/28/85 ✓	
HCFA comments due on combined circulation draft (FYI to FDA)	07/01/85		
OCP/HCFA markup of combined circulation draft to RS/HCFA			07/15/85
Revised HCFA regulation to FDA	07/22/85		
ACRA and GC (FDA) clearance of signature package		07/26/85	
FDA combined regulation (and Secretarial memo) to HCFA	08/01/85		
Signature package to OCP/HCFA			08/02/85
OCP/HCFA clearance of final signature package			08/06/85
Signature package to BERC Director (HCFA)			08/07/85
BERC Director (HCFA) clearance of final signature package			08/09/85
Signature package to HCFA for final clearance			08/12/85
Signature package (Blue) to ACRA/FDA for final clearance		08/30/85	
Signature package to FDA Commissioner and HCFA Administrator	09/23/85		
Signature package of combined regulation to OS	09/30/85		

1072C

[illegible] FDA reg [illegible]

Donna

PACEMAKER REGISTRY WORKING GROUP
MINUTES OF MEETING I
APRIL 5, 1985

(Agenda and List of Participants attached)

Donna Lenahan, CDRH, opened the meeting by reporting that she had been designated to coordinate the pacemaker registry within CDRH. She stressed the need for all working group members to keep everyone in the group informed of their activities and to cc: both she and Sharon Hippler, HCFA, on all documents relating to the registry. (Debbie Katzenstein has since been named HCFA coordinator for the registry.)

Stauts of Regulations Development

Mel Altman, OSR, CDRH, discussed the status of the development of regulations to implement the registry. He reported that the regulations will not be reviewed by OMB under Executive Order 12498 because the registry is mandated by statute, an exclusion under the E.O. The regulations will be developed jointly by FDA and HCFA, with FDA assuming the lead.

Dr. Altman explained the two-staged approach being used to develop the regulations. The first stage will entail development of a regulation to establish the registry, listing the required data elements and the provisions under which Medicare payment may be withheld. The preamble to the first regulation will serve as a Notice of Intent to develop the second regulation on the return and testing of explanted devices.

The regulations will be signed by the FDA Commissioner and the HCFA Administrator and will appear in the CFR under both Titles 18 (Social Security Act) and 21 (FD&C Act). The regulations will be issued under the authority of the Social Security Act.

Dr. Altman said we are waiting to review HCFA's portion of the first draft regulation, and HCFA representatives indicated that a draft would be available for comment in about a week.

Dr. Altman distributed a proposed FDA/HCFA schedule for promulgating the joint regulations and a draft outline of the preamble to the first proposed rule. He indicated that the 6/28/85 date for final CDRH/FDA signoff/request for ACRA and GC (FDA) review, and the 9/23/85 date for sending the signature package to the FDA Commissioner and the HCFA Administrator, were included in the Center's submission to FDA's regulations plan and that we should strive to meet these dates.

It was agreed among the CDRH and HCFA representatives that a comment period of 60 to 90 days would be adequate for the proposed regulation.

After the meeting, Bill Rush, HCFA, assumed responsibility for complying with E.O. 12291, Economic Assessment/Regulatory Flexibility, for the regulations. Ron Milhorn, HCFA, agreed to write the justification for OMB clearance for information collection under the Paperwork Reduction Act and to obtain clearance within HCFA.

Meeting with HIMA

Ms. Lenahan reported on a March 5 meeting with the Pacemaker Interests Group of the Health Industries Manufacturers Association (HIMA) to discuss the registry. A summary of the minutes of that meeting is attached.

Dr. Altman noted that once a regulation has been proposed, there are limitations on the solicitation of input from affected groups. Therefore, it is important to solicit input while developing the proposed rule. Interested groups may include the American Association for Medical Instrumentation (AAMI), the American Association of Cardiologists, the American Hospital Associaton, health insurers, and possibly patient groups (e.g, through the American Association for Retired Persons). HCFA representatives stated that they usually rely on the formal public comment process for such input. Ms. Lenahan requested that Bill Dierkshiede, CDRH's Office of Training and Assistance representative to the group, look into obtaining input from interested groups before the regulation is proposed in the Federal Register. She also stated that Glen Rahmoeller, CDRH's Office of Device Evaluation representative, agreed to solicit input at the next meeting of the North American Society of Pacing and Electrophysiology in May.

Report to Congress

Ms. Lenahan introduced the subject of submitting a status report to the Senate Committee on Aging on the progress made thus far on the registry. She reported that representatives of the Committee staff had called her on March 29 and visited CDRH on April 1 and April 2, seeking information about the registry. Staffers had also visited HCFA. In view of these visits, a decision should be made as to whether a status report should be submitted and, if so, whether it should be a joint FDA/ HCFA report and how much detail it should include.

The group agreed that a joint report should be submitted and that it should be signed by both the Commissioner of FDA and the Administrator of HCFA.

Ms. Lenahan said she would redraft the letter report to the Senate Committee, describing in general terms the data collection scheme and specifying the minimum data items to be collected under the registry. She will state that additional data elements are being considered, but will be clear about the limitations and uses of the data.

Coordination with HCFA: Assignment

Ms. Hippler said she would write a letter to Marty Kappert, Associate Administrator for Operations, HCFA, detailing events to date regarding the registry and asking that someone in the Administrator's Office be designated to coordinate development of the registry within HCFA. She will cc: Ms. Lenahan on this letter. (Debbie Katzenstein will assume this task.)

Data Elements: Assignment

There was considerable discussion of the specific data elements to be collected under the registry, but no final agreement was reached. Ms. Lenahan said she would add this topic to the list of unresolved issues (see agenda). She asked each representative to consult his or her office for written input on the specific data elements that should be collected under the registry.

Data Collection

Jim Case, HCFA, discussed HCFA's intermediary system and explained how it would function to collect data for the registry. There also was some discussion of a trial data collection effort by a few intermediaries before the regulations become effective. Dr. Evelyn Gordon, OHA, CDRH, said OMB clearance is needed if information is to be collected from more than nine individuals. Mr. Case said he would initiate OMB clearance for the trial data collection. (As the lead in developing the regulations, CDRH will initiate OMB clearance for the registry regulations.) However, the working group must first specify exactly what data elements will be collected. OMB clearance will take approximately three months from the time of submission. Intermediaries can begin sending us data within approximately two months.

Memorandum of Understanding

Ms. Hippler and Ms. Lenahan agreed to work together to develop a memorandum of understanding between FDA and HCFA that will specify the roles and expectations of each agency in implementing the registry.

Unresolved Issues: Assignments

A number of unresolved issues were listed on the meeting agenda but were not discussed in detail. Ms. Lenahan asked each CDRH representative to provide, in writing, his or her office's viewpoints on each of the unresolved issues listed in the agenda to this meeting by Tuesday, April 30.

Ms. Hippler said she would include the list of all unresolved issues in the letter to Marty Kappert.

Next Scheduled Meeting

The next meeting of the working group was scheduled for Thursday, May 9, at 9:00 a.m. at the HCFA facility in Baltimore. A meeting package will be forthcoming.

Prepared by Mickie Kivel

FDA/HCFA Pacemaker Registry Working Group

Meeting I

Agenda

- o Introductions, including
    - your organization
    - your role in implementing the registry
    - your organization's involvement with the registry
    - status report of registry-related activities/interest

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    - See page 3 of memo for specifics

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    - format

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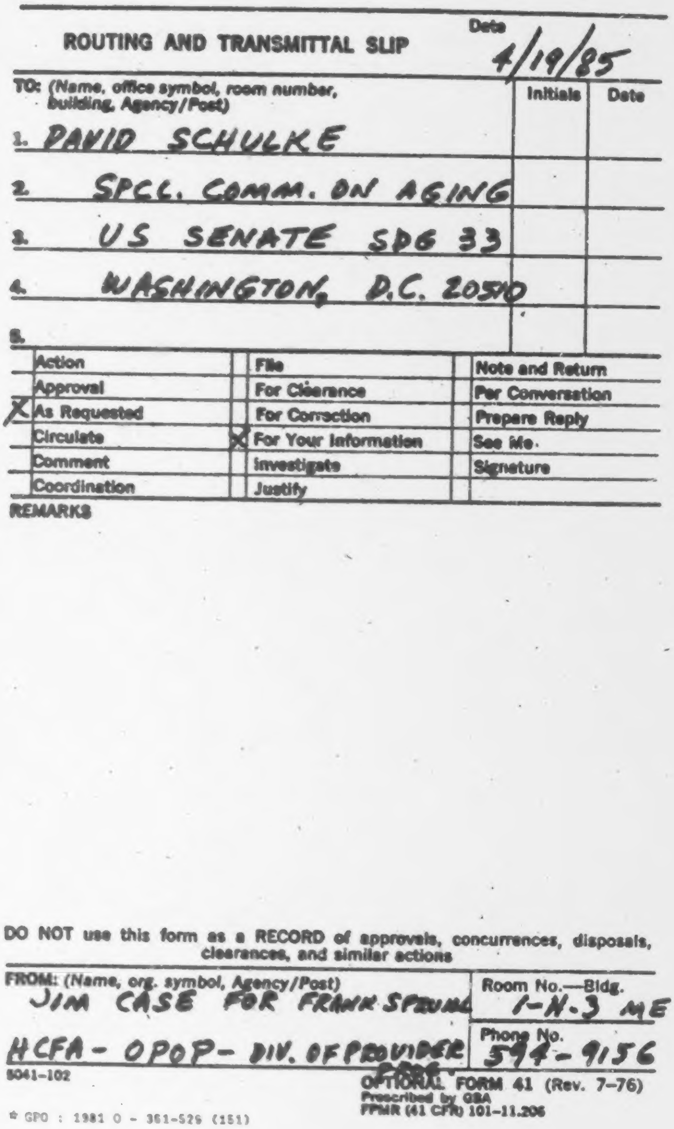
PARTICIPANTS
FDA/HCFA Pacemaker Registry Working Group Meeting I
April 5, 1985

Donna Lenahan, FDA
Fred Hooten, FDA
Robert Skufca, FDA
Wendy Johnson, FDA
William Dierkshiede, FDA
Mel Altman, FDA
Evelyn Gordon, FDA
Mickie Kivel, FDA

Ron Milhorn, HCFA
Jim Case, HCFA
Bill Rush, HCFA
Sharon Hippler, HCFA
Michelle French, HCFA
Karen Haas, HCFA
Debbie Katzenstein, HCFA

[Excerpt of form used by Peer Review Organizations (PROs) to report monthly pacemaker review activity to HCFA. Provided to Special Committee on Aging staff on April 19, 1985, with annotations by Jim Case, Office of Program Operations Procedures, Bureau of Program Operations, HCFA.]



ROUTING AND TRANSMITTAL SLIP

Date 4/19/85

TO: (Name, office symbol, room number, building, Agency/Post)	Initials	Date
1. DAVID SCHULKE		
2. SPCL. COMM. ON AGING		
3. US SENATE SDG 33		
4. WASHINGTON, D.C. 20510		
5.		

	Action		File		Note and Return
	Approval		For Clearance		Per Conversation
X	As Requested		For Correction		Prepare Reply
	Circulate	X	For Your Information		See Me
	Comment		Investigate		Signature
	Coordination		Justify		

REMARKS

DO NOT use this form as a RECORD of approvals, concurrences, disposals, clearances, and similar actions

FROM: (Name, org. symbol, Agency/Post)	Room No.—Bldg.
JIM CASE FOR FRANK SPEUNG	1-H-3 ME
HCFA - OPOP - DIV. OF PROVIDER PROG	Phone No. 594-9156

5041-102

OPTIONAL FORM 41 (Rev. 7-76)
Prescribed by GSA
FPMR (41 CFR) 101-11.206

☆ GPO : 1981 O - 361-529 (151)

ITEM IV

SHOWS WHAT PROS
NOW COLLECT

PAGE 6 -

IS NO LONGER
COLLECTED (BY PROs)
SINCE FDA
HAS RESPONSIBILITY

REPORT OF PRO REVIEW ACTIVITY - (PPS-RELATED ACTIVITIES) - HCFA-516 5000.14

PRO Name

2. PRO I.D.

3. Report Month/Year

4. No. of PPS Hospitals in PRO Area (HH010) ______

5. PATBILL Cases This Month (PB010)

6. Discharge Dates

Current Month (PB020) ______

Prior Month (PB030) ______

Two Months Prior (PB040) ______

Three Months Prior (PB050) ______

Over Three Months Prior (PB060) ______

I. ADMISSION REVIEW		Reviews Identified This Month (1)	Reviews Completed This Month (2)	Denials This Month (3)		Cases Paid Under Waiver This Month (4)
A. Admission Sample	(AR010)					
B. Intensified Review	(AR020)					
C. Pre-Admission	(AR030)					
D. Medicare Code Editor	(AR040)					
E. Reviews for Other Reasons	(AR050)					
F. TOTAL	(AR060)					
II. TRANSFERS		(1)	(2)	(3)		(4)
A. Psychiatric Unit	(TR010)					
B. Rehabilitation Unit	(TR020)					
C. Alcohol/Drug Treatment Unit	(TR030)					
D. Swing Bed	(TR040)					
E. Any Other Acute Hospital	(TR050)					
III. READMISSIONS		(1)	(2)	(3)		(4)
Readmissions	(RA010)					
IV. PROCEDURE REVIEW		(1)	(2)	Admission (3a)	Procedure Only (3b)	(4)
A. Pacemaker Insertions	(PR010)					
B. Pacemaker Reimplants	(PR020)					
C. Other Invasive Procedures	(PR030)					

* Total No. of PPS Hospitals Under Intensified Review (AR070) ______

PACEMAKER REIMPLANT WARRANTY INFORMATION

PRIOR INSERTION DATA			REIMPLANT DATA		
DATE OF INSERTION	PACEMAKER NAME/SERIAL NO.	WARRANTY PERIOD	DATE OF INSERTION	PACEMAKER NAME/SERIAL NO.	WARRANTY PERIOD

as of 3/85 HSQB
no longer gets this
due to FDA collection

[Committee Staff Explanation of Attached Document Entitled "PRO Medical Review Procedure Review Activity Report"]

[The attached print-out, obtained from HCFA's central office, summarizes the medical review activity reported by PROs in their monthly reports to HCFA (HCFA form 516), beginning with each PRO's first month and ending with reports received for April, 1985. Column and Row headings are explained below:]

"PROID" is the identification number for the Peer Review Organization for each State. The first digit identifies the Federal Region (1 through 10) that the PRO is located within ("0" designates Region 10). The following two positions represent the Postal Service style of abbreviating State names. Thus, 0AK00 is followed by the Alaska PRO's reported data.

"8411", "8412", etc. designate the year and month the reported data was obtained in ("8411", for example, identifies data found in reviews conducted within the month of November, 1984.)

"PACE INSERT IDENT": refers to the number of initial pacemaker insertions identified by the PRO in their State for each month. Does not include reimplant surgeries.

"PACE INSERT COMP": the number of initial pacemaker insertion reviews completed by the PRO during the reported month. Each month's figures may include reviews completed on insertions originally identified in previous months (this would happen if the PRO was behind in its reviews.)

"PACE INSERT ADMISS DENIAL": the number of hospital admissions for a pacemaker insertion for which Medicare reimbursement was denied by the PRO after completion of their review. (These are surgeries which the PRO has determined were wholly unnecessary, resulting in no reimbursement.)

"PACE INSERT PROC DENIAL": the number of pacemaker insertion procedures for which the PRO has denied reimbursement after completion of their review. (Denial of a procedure will allow some portion of costs for the patient's hospital stay to be reimbursed.)

"PACE INSERT WAIVER": the number of pacemaker insertions denied but for which payment was allowed by the PRO under waiver.

"PACE REIMP IDENT": the number of pacemaker reimplantations identified by the PRO in the reported month.

"PACE REIMP COMP": the number of pacemaker reimplantation reviews completed by the PRO during the reported month. Could include reviews completed on reimplantations which were originally identified in previous months.

"PACE REIMP ADMISS DENIAL": the number of hospital admissions for pacemaker reimplantation for which Medicare reimbursement was denied by the PRO.

"PACE REIMP PROC DENIAL": the number of pacemaker reimplantation procedures for which the PRO has denied reimbursement after completion of their review. (Denial of a procedure will allow some portion of costs for the patient's hospital stay to be reimbursed.)

"PACE REIMP WAIVER": the number of pacemaker reimplantations denied but for which payment was allowed by the PRO under waiver.

[**NOTE:** Other column headings refer to invasive procedure reviews performed by the PROs, other than those performed on pacemaker surgeries.]

PAGE NO. 00001
05/23/85

PRO MEDICAL REVIEW
PROCEDURE REVIEW
ACTIVITY REPORT

PROID YY/MM	PACE INSERT IDENT	PACE INSERT COMP	PACE INSERT ADMISS DENIAL	PACE INSERT PROC DENIAL	PACE INSERT WAIVER	PACE REIMP IDENT	PACE REIMP COMP	PACE REIMP ADMISS DENIAL	PACE REIMP PROC DENIAL	PACE REIMP WAIVER	INV PROC IDENT	INV PROC COMP	INV PROC ADMISS DENIALS	INV PROC ONLY DENIALS	INV PROC WAIVER:
* PROID 0AK00															
0AK00 8411	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
0AK00 8412	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
0AK00 8501	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
0AK00 8502	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
0AK00 8503	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0
0AK00 8504	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
** SUBTOTAL **	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0
* PROID 0ID00															
0ID00 8411	2	2	0	0	0	2	2	0	0	0	0	0	0	0	0
0ID00 8412	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
0ID00 8501	9	9	0	0	0	1	1	0	0	0	0	0	0	0	0
0ID00 8502	9	9	0	0	0	0	0	0	0	0	0	0	0	0	0
0ID00 8503	6	6	0	0	0	3	3	0	0	0	0	0	0	0	0
0ID00 8504	5	5	0	0	0	0	0	0	0	0	0	0	0	0	0
** SUBTOTAL **	31	31	0	0	0	6	6	0	0	0	0	0	0	0	0
* PROID 0OR00															
0OR00 8408	39	29	0	0	0	3	4	0	0	0	0	0	0	0	0
0OR00 8409	46	53	0	0	0	15	9	0	0	0	0	0	0	0	0
0OR00 8410	73	84	1	0	0	1	24	0	0	0	0	0	0	0	0
0OR00 8411	44	41	0	0	0	10	9	0	0	0	0	0	0	0	0
0OR00 8412	8	8	0	1	1	1	1	0	0	0	0	0	0	0	0
0OR00 8501	56	30	0	0	0	18	11	0	0	0	0	0	0	0	0
0OR00 8502	26	47	0	0	0	10	10	0	0	0	0	0	0	0	0
0OR00 8503	57	43	0	0	0	8	8	0	0	0	0	0	0	0	0
0OR00 8504	36	40	0	3	0	9	5	0	0	0	0	0	0	0	0
** SUBTOTAL **	385	375	1	4	1	75	81	0	0	0	0	0	0	0	0
* PROID 0WA00															
0WA00 8410	63	21	0	1	0	0	0	0	0	0	0	0	0	0	0
0WA00 8411	111	11	0	0	0	0	0	0	0	0	0	0	0	0	0
0WA00 8412	93	37	0	0	0	0	0	0	0	0	0	0	0	0	0
0WA00 8501	61	46	0	0	0	3	0	0	0	0	0	0	0	0	0
0WA00 8502	62	18	0	0	0	0	0	0	0	0	0	0	0	0	0
0WA00 8503	69	259	0	0	0	0	0	0	0	0	0	0	0	0	0
0WA00 8504	81	67	0	0	0	0	0	0	0	0	0	0	0	0	0
** SUBTOTAL **	540	459	0	1	0	3	0	0	0	0	0	0	0	0	0

PAGE NO. 00002
05/23/85

PRO MEDICAL REVIEW
PROCEDURE REVIEW
ACTIVITY REPORT

PROID YY/MM	PACE INSERT IDENT	PACE INSERT COMP	PACE INSERT ADMISS DENIAL	PACE INSERT PROC DENIAL	PACE INSERT WAIVER	PACE REIMP IDENT	PACE REIMP COMP	PACE REIMP ADMISS DENIAL	PACE REIMP PROC DENIAL	PACE REIMP WAIVER	INV PROC IDENT	INV PROC COMP	INV PROC ADMISS DENIALS	INV PROC ONLY DENIALS	INV PROC WAIVERS
* PROID 1CT00															
1CT00 8411	34	32	0	0	0	0	0	0	0	0	0	0	0	0	0
1CT00 8412	17	17	0	0	0	0	0	0	0	0	0	0	0	0	0
1CT00 8501	86	10	0	0	0	1	1	0	0	0	666	673	3	0	0
1CT00 8502	0	21	0	0	0	0	1	0	0	0	269	272	0	0	0
1CT00 8503	8	14	0	0	0	0	2	0	0	0	575	534	1	0	0
1CT00 8504	53	23	0	0	0	0	2	0	0	0	431	403	1	0	0
** SUBTOTAL **	198	117	0	0	0	1	6	0	0	0	1941	1882	5	0	0
* PROID 1ME00															
1ME00 8411	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1ME00 8412	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1ME00 8501	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0
1ME00 8502	0	0	0	0	0	0	0	0	0	0	7	0	0	0	0
1ME00 8503	34	34	0	0	0	3	3	0	0	0	41	41	2	0	0
1ME00 8504	54	54	0	0	0	0	0	0	0	0	19	19	0	0	0
** SUBTOTAL **	90	90	0	0	0	3	3	0	0	0	67	60	2	0	0
* PROID 1NH00															
1NH00 8407	5	5	0	0	0	2	2	0	0	0	0	0	0	0	0
1NH00 8408	28	28	0	0	0	2	2	0	0	0	0	0	0	0	0
1NH00 8409	13	13	1	0	0	0	0	0	0	0	0	0	0	0	0
1NH00 8410	16	16	0	0	0	2	2	0	0	0	0	0	0	0	0
1NH00 8411	29	29	0	0	0	3	3	0	0	0	0	0	0	0	0
1NH00 8412	15	15	0	0	0	3	3	0	0	0	0	0	0	0	0
1NH00 8501	22	22	0	0	0	5	5	0	0	0	0	0	0	0	0
1NH00 8502	31	31	0	0	0	0	0	0	0	0	0	0	0	0	0
1NH00 8503	20	20	0	0	0	2	2	0	0	0	0	0	0	0	0
1NH00 8504	14	14	0	0	0	1	1	0	0	0	0	0	0	0	0
** SUBTOTAL **	193	193	1	0	0	20	20	0	0	0	0	0	0	0	0
* PROID 1RI00															
1RI00 8408	11	11	0	0	0	4	4	0	0	0	0	0	0	0	0
1RI00 8409	23	23	0	0	0	5	5	0	0	0	0	0	0	0	0
1RI00 8410	19	19	0	0	0	2	2	0	0	0	0	0	0	0	0
1RI00 8411	28	28	1	0	0	14	14	0	0	0	0	0	0	0	0
1RI00 8412	17	17	0	0	0	0	0	0	0	0	106	106	10	0	0
1RI00 8501	28	28	0	0	0	10	10	0	0	0	124	124	0	0	0
1RI00 8502	29	29	0	0	0	3	3	0	0	0	106	106	5	0	4

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                                                   PRO MEDICAL REVIEW
                                                   PROCEDURE REVIEW
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PROID YY/MM   PACE     PACE     PACE     PACE     PACE     PACE     PACE     PACE     PACE     PACE     INV      INV      INV      INV      INV
              INSERT   INSERT   INSERT   INSERT   INSERT   REIMP    REIMP    REIMP    REIMP    REIMP    PROC     PROC     PROC     PROC     PROC
              IDENT    COMP     ADMISS   PROC     WAIVER   IDENT    COMP     ADMISS   PROC     WAIVER   IDENT    COMP     ADMISS   ONLY     WAIVERS
                                DENIAL   DENIAL                              DENIAL   DENIAL                               DENIALS  DENIALS

* PROID 1RI00
1RI00 8503        34       34        0        0        0        5        5        0        0        0      150      150        3        0        2
1RI00 8504        15       15        0        0        0        0        0        0        0        0      107      107        2        0        0
** SUBTOTAL **
                 204      204        1        0        0       43       43        0        0        0      593      593       20        0        6

* PROID 1VT00
1VT00 8411        11       11        0        0        0        0        0        0        0        0        0        0        0        0        0
1VT00 8412         3        3        0        0        0        0        0        0        0        0        0        0        0        0        0
1VT00 8501        13       13        0        0        0        0        0        0        0        0        0        0        0        0        0
1VT00 8502         8        8        0        0        0        0        0        0        0        0        0        0        0        0        0
1VT00 8503         3        3        0        0        0        0        0        0        0        0        0        0        0        0        0
1VT00 8504         1        1        0        0        0        0        0        0        0        0        0        0        0        0        0
** SUBTOTAL **
                  39       39        0        0        0        0        0        0        0        0        0        0        0        0        0

* PROID 3DC00
3DC00 8411         0        0        0        0        0        0        0        0        0        0        0        0        0        0        0
3DC00 8412         0        0        0        0        0        0        0        0        0        0        0        0        0        0        0
3DC00 8501        10        1        0        0        0        0        0        0        0        0        0        0        0        0        0
3DC00 8502         3        4        0        0        0        0        0        0        0        0        0        0        0        0        0
3DC00 8503        15        5        0        0        0        0        0        0        0        0        0        0        0        0        0
3DC00 8504         6       21        0        0        0        0        0        0        0        0        0        0        0        0        0
** SUBTOTAL **
                  34       31        0        0        0        0        0        0        0        0        0        0        0        0        0

* PROID 3DE00
3DE00 8407         0        0        0        0        0        0        0        0        0        0        0        0        0        0        0
3DE00 8408         1        1        0        0        0        0        0        0        0        0        0        0        0        0        0
3DE00 8409         5        5        0        0        0        0        0        0        0        0       40       40        0        0        0
3DE00 8410         5        5        0        0        0        0        0        0        0        0       47       47        0        0        0
3DE00 8411        15       15        0        0        0        2        2        0        0        0       51       51        0        0        0
3DE00 8412        19       19        0        0        0        1        1        0        0        0       57       57        0        0        0
3DE00 8501        17        0        0        0        0        0        0        0        0        0       57        0        0        0        0
3DE00 8502         9        9        0        0        0        4        4        0        0        0      193      193        0        0        0
3DE00 8503        13       13        0        0        0        2        2        0        0        0       68       68        0        0        0
3DE00 8504        14       14        0        0        0        3        3        0        0        0       96       96        0        0        0
** SUBTOTAL **
                  98       81        0        0        0       12       12        0        0        0      609      552        0        0        0
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PROID YY/MM	PACE INSERT IDENT	PACE INSERT COMP	PACE INSERT ADMISS DENIAL	PACE INSERT PROC DENIAL	PACE INSERT WAIVER	PACE REIMP IDENT	PACE REIMP COMP	PACE REIMP ADMISS DENIAL	PACE REIMP PROC DENIAL	PACE REIMP WAIVER	INV PROC IDENT	INV PROC COMP	INV PROC ADMISS DENIALS	INV PROC ONLY DENIALS	INV PRO WAIVE
* PROID 3PA00															
3PA00 8410	84	26	0	0	0	0	1	0	0	0	4	4	0	0	
3PA00 8411	179	99	0	0	0	0	4	0	0	0	9	0	0	0	
3PA00 8412	199	103	4	0	4	2	3	0	0	0	20	74	0	0	
3PA00 8501	472	219 225	0	0	0	9	12	0	0	0	2	0	0	0	
3PA00 8502	410	411	3	9	3	13	18	0	0	0	0	0	0	0	
3PA00 8503	555	577	0	0	0	25	44	0	0	0	0	57	0	0	
3PA00 8504	587	541	0	0	0	24	50	0	0	0	14	45	0	12	
** SUBTOTAL **															
	2486	1976	7	9	7	73	132	0	0	0	49	180	0	12	
* PROID 3VA00															
3VA00 8410	0	50	0	0	0	0	4	0	0	0	0	0	0	0	0
3VA00 8411	7	54	0	0	0	0	5 0	0	0	0	0	0	0	0	0
3VA00 8412	104	48	0	0	0	15	6	0	0	0	276	276	0	0	0
3VA00 8501	70	73	0	0	0	9	2	0	0	0	723	723	0	0	0
3VA00 8502	82	55	0	0	0	0	4	0	0	0	589	589	0	0	0
3VA00 8503	134	75	0	0	0	0	5	0	0	0	805	811	0	0	0
3VA00 8504	89	119	0	0	0	0	3	0	0	0	752	273	0	0	0
** SUBTOTAL **															
	486	474	0	0	0	24	29	0	0	0	3145	2672	0	0	0
* PROID 3WV00															
3WV00 8407	0	54	0	0	0	0	1	0	0	0	0	0	0	0	0
3WV00 8408	0	9	0	0	0	0	0	0	0	0	0	0	0	0	0
3WV00 8409	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
3WV00 8410	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0
3WV00 8411	32	21 0	0	0	0	0	0	0	0	0	0	0	0	0	0
3WV00 8412	20	19 13	0	0	0	0	0	0	0	0	0	0	0	0	0
3WV00 8501	50	33	0	0	0	1	0	0	0	0	35	0	0	0	0
3WV00 8502	39	48	0	0	0	1	0	0	0	0	0	0	0	0	0
3WV00 8503	58	21	0	0	0	1	1	0	0	0	0	0	0	0	0
3WV00 8504	37	28	0	0	0	2	1	0	0	0	0	0	0	0	0
** SUBTOTAL **															
	237	234	0	0	0	5	3	0	0	0	35	0	0	0	0
* PROID 4AL00															
4AL00 8407	76	0	0	0	0	0	0	0	0	0	0	0	0	0	0
4AL00 8408	20	59	0	0	0	0	3	0	0	0	0	0	0	0	0
4AL00 8409	17	46	0	0	0	0	7	0	0	0	0	0	0	0	0
4AL00 8410	163	71	0	0	0	0	9	0	0	0	0	0	0	0	0
4AL00 8411	113	77	0	0	0	0	8	0	0	0	0	0	0	0	0

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PROID YY/MM	PACE INSERT IDENT	PACE INSERT COMP	PACE INSERT ADMISS DENIAL	PACE INSERT PROC DENIAL	PACE INSERT WAIVER	PACE REIMP IDENT	PACE REIMP COMP	PACE REIMP ADMISS DENIAL	PACE REIMP PROC DENIAL	PACE REIMP WAIVER	INV PROC IDENT	INV PROC COMP	INV PROC ADMISS DENIALS	INV PROC ONLY DENIALS	INV PROC WAIVER
* PROID 4AL00															
4AL00 8412	105	62	0	0	0	0	8	0	0	0	0	0	0	0	[illegible]
4AL00 8501	131	118	0	0	0	0	24	0	0	0	0	0	0	0	[illegible]
4AL00 8502	105	86	0	0	0	0	16	0	0	0	0	0	0	0	[illegible]
4AL00 8503	103	84	0	0	0	22	22	0	0	0	0	0	0	0	[illegible]
4AL00 8504	118	82	0	0	0	18	10	0	0	0	0	0	0	0	[illegible]
** SUBTOTAL **	951	685	0	0	0	40	107	0	0	0	0	0	0	0	[illegible]
* PROID 4FL00															
4FL00 8408	6	6	1	2	0	1	1	0	0	0	0	0	0	1	0
4FL00 8409	35	38	0	0	0	0	0	0	0	0	0	0	0	0	0
4FL00 8410	80	80	0	0	0	4	4	0	0	0	0	0	0	0	0
4FL00 8411	56	56	2	2	4	13	13	0	0	0	0	0	0	0	0
4FL00 8412	87	87	3	0	3	8	8	0	0	0	0	0	0	0	0
4FL00 8501	135	135	5	0	5	17	17	1	0	1	0	0	0	0	0
4FL00 8502	240	240	51	0	0	28	28	14	0	0	2	2	0	0	0
4FL00 8503	677	677	4	2	0	19	19	1	0	0	4	4	0	0	0
4FL00 8504	227	227	0	1	0	17	17	0	0	0	0	0	0	0	0
** SUBTOTAL **	1543	1546	66	7	12	107	107	16	0	1	6	6	0	1	0
* PROID 4GA00															
4GA00 8408	47	47	0	0	47	0	0	0	0	0	0	0	0	0	0
4GA00 8409	35	35	0	0	0	0	0	0	0	0	40	40	1	0	0
4GA00 8410	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0
4GA00 8411	38	38	0	0	0	1	1	0	0	0	446	446	15	0	15
4GA00 8412	71	71	0	0	0	0	0	0	0	0	728	728	0	0	0
4GA00 8501	95	95	0	0	0	0	0	0	0	0	972	972	0	0	0
4GA00 8502	72	72	0	0	0	1	1	0	0	0	903	903	0	0	0
4GA00 8503	86	86	0	1	0	3	3	0	0	0	1023	1023	146	0	146
4GA00 8504	124	124	0	2	0	6	6	0	0	0	1167	1167	0	1	0
** SUBTOTAL **	569	569	0	3	47	11	11	0	0	0	5279	5279	170	1	169
* PROID 4KY00															
4KY00 8407	0	0	0	0	0	0	0	0	0	0	34	34	0	0	0
4KY00 8408	24	24	0	0	0	13	13	0	0	0	955	955	0	0	0
4KY00 8409	44	44	0	0	0	5	5	0	0	0	1203	1203	0	0	0
4KY00 8410	88	88	0	0	0	13	13	0	0	0	2352	2352	1	0	1
4KY00 8411	55	55	0	0	0	9	9	0	0	0	1759	1769	0	0	0
4KY00 8412	80	80	0	0	0	8	8	0	0	0	1893	1893	0	0	0

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PROID YY/MM	PACE INSERT IDENT	PACE INSERT COMP	PACE INSERT ADMISS DENIAL	PACE INSERT PROC DENIAL	PACE INSERT WAIVER	PACE REIMP IDENT	PACE REIMP COMP	PACE REIMP ADMISS DENIAL	PACE REIMP PROC DENIAL	PACE REIMP WAIVER	INV PROC IDENT	INV PROC COMP	INV PROC ADMISS DENIALS	INV PROC ONLY DENIALS	INV PROC WAIVER
* PROID 4KY00															
4KY00 8501	19	16	0	0	0	3	3	0	0	0	1935	1935	0	0	
4KY00 8502	13	0	0	0	0	0	0	0	0	0	1703	1703	0	0	
4KY00 8503	47	47	0	0	0	0	0	0	0	0	442	442	0	0	
4KY00 8504	49	23	0	0	0	0	0	0	0	0	263	46	0	0	
** SUBTOTAL **															
	419	377	0	0	0	51	51	0	0	0	12549	12332	1	0	
we have July?															
* PROID 4MS00	31	0.	0	0	0	0	0	0	0	0					
4MS00 8408	46	46	0	0	0	0	0	0	0	0	0	5	0	0	[illegible]
4MS00 8409	63	28	0	0	0	0	0	0	0	0	794	6	0	0	[illegible]
4MS00 8410	50	57	0	0	0	0	6	0	0	0	403	56	0	0	[illegible]
4MS00 8411	40	45	0	0	0	0	3	0	0	0	206	32	0	0	[illegible]
4MS00 8412	60	33	0	0	0	0	4	0	0	0	238	78	4	0	[illegible]
4MS00 8501	38	49	0	0	0	9	9	0	0	0	116	97	1	0	
4MS00 8502	79	37	0	0	0	3	3	0	0	0	231	136	0	0	[illegible]
4MS00 8503	60	69	0	0	0	7	7	0	0	0	175	215	0	0	[illegible]
4MS00 8504	44	34	0	0	0	14	14	0	0	0	138	24	1	0	
** SUBTOTAL **															
	400	398	0	0	0	33	46	0	0	0	2301	649	6	0	[illegible]
* PROID 4NC00															
4NC00 8408	0	0	0	0	0	0	0	0	0	0	0	0	0	0	[illegible]
4NC00 8409	29	13	0	0	0	0	0	0	0	0	599	231	9	0	[illegible]
4NC00 8410	140	60	0	0	0	2	1	0	0	0	3773	1588	90	0	[illegible]
4NC00 8411	127	103	0	0	0	3	2	0	0	0	3420	2438	302	0	[illegible]
4NC00 8412	124	58	0	0	0	5 1	0	0	0	0	2651	1128	42	0	[illegible]
4NC00 8501	91	44	0	0	0	8 13	0 6	0	0	0	1103	254	18	0	[illegible]
4NC00 8502	123	43	0	0	0	13 5	6 0	0	0	0	693	248	27	0	[illegible]
4NC00 8503	124	57	0	0	0	5	4	0	0	0	640	275	27	0	[illegible]
4NC00 8504	110	127	0	0	0	1	4	0	0	0	475	399	0	0	[illegible]
** SUBTOTAL **															
	868	505	0	0	0	30	17	0	0	0	13354	6561	515	0	476
* PROID 4SC00															
4SC00 8407	198	162	0	0	0	23	15	0	0	0	0	0	0	0	0
4SC00 8408	51	9	0	0	0	11	11	0	0	0	0	0	0	0	0
4SC00 8409	40	40	0	0	0	8	8	0	0	0	0	0	0	0	0
4SC00 8410	52	50	0	0	0	7	7	0	1	0	205	205	0	0	0
4SC00 8411	46	46	0	0	0	17	17	0	0	0	337	337	0	0	0
4SC00 8412	60	60	0	0	0	10	10	0	0	0	389	389	1	0	0
4SC00 8501	70	70	0	0	0	15	15	0	0	0	346	346	1	0	0

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* PROID 4SC00															
4SC00 8502	68	68	0	0	0	24	24	0	0	0	396	396	1	1	
4SC00 8503	73	73	0	0	0	13	13	0	0	0	389	389	0	0	
4SC00 8504	92	92	0	0	0	14	14	0	0	0	509	509	0	0	
** SUBTOTAL **	750	670	0	0	0	142	134	0	1	0	3010	3010	3	1	
* PROID 4TN00															
4TN00 8407	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
4TN00 8408	2	2	0	0	0	0	0	0	0	0	0	0	0	0	
4TN00 8409	8	8	0	0	0	0	0	0	0	0	0	0	0	0	
4TN00 8410	4	4	0	0	0	0	0	0	0	0	9	9	0	0	
4TN00 8411	110	110	0	0	0	0	0	0	0	0	0	0	0	0	
4TN00 8412	33	33	0	0	0	0	0	0	0	0	0	0	0	0	
4TN00 8501	8	92	0	0	0	1	1	0	0	0	0	0	0	0	
4TN00 8502	0	54	0	0	0	0	0	0	0	0	0	0	0	0	
4TN00 8503	193	66	0	0	0	0	0	0	0	0	0	0	0	0	
4TN00 8504	250	158	0	0	0	0	0	0	0	0	0	10	0	0	
** SUBTOTAL **	608	527	0	0	0	1	1	0	0	0	9	19	0	0	
* PROID 5IL00															
5IL00 8411	75	75	1	0	1	⑦ 4	⑦ 4	0	0	0	0	0	0	0	
5IL00 8412	56	53	0	0	0	④ 7	④ 7	0	0	0	0	0	0	0	
5IL00 8501	123	118	0	0	0	14	14	0	0	0	0	0	0	0	
5IL00 8502	62	50	0	0	0	2	2	0	0	0	0	0	0	0	
5IL00 8503	106	106	0	0	0	3	3	0	0	0	81	81	0	0	
5IL00 8504	187	222	0	0	0	9	8	0	0	0	147	531	0	0	
** SUBTOTAL **	609	624	1	0	1	39	38	0	0	0	228	612	0	0	
* PROID 5IN00															
5IN00 8408	8	8	0	0	0	0	0	0	0	0	0	0	0	0	
5IN00 8409	19	4	0	0	0	8	0	0	0	0	0	0	0	0	
5IN00 8410	83	35	0	0	0	9	12	0	0	0	0	0	0	0	
5IN00 8411	39	83	0	0	0	7	12	0	0	0	0	0	0	0	
5IN00 8412	118	88	1	0	1	19	6	0	0	0	0	0	0	0	
5IN00 8501	22	70	1	0	1	9	10	0	0	0	0	0	0	0	
5IN00 8502	74	47	0	0	0	13	11	0	0	0	0	0	0	0	
5IN00 8503	121	71	0	1	0	25	12	0	0	0	2498	3080	263	0	3
5IN00 8504	48	56	0	0	0	7	7	0	0	0	701	1990	178	0	8
** SUBTOTAL **	532	462	2	1	2	97	70	0	0	0	3199	5070	441	0	11

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PROCEDURE REVIEW
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PROID YY/MM	PACE INSERT IDENT	PACE INSERT COMP	PACE INSERT ADMISS DENIAL	PACE INSERT PROC DENIAL	PACE INSERT WAIVER	PACE REIMP IDENT	PACE REIMP COMP	PACE REIMP ADMISS DENIAL	PACE REIMP PROC DENIAL	PACE REIMP WAIVER	INV PROC IDENT	INV PROC COMP	INV PROC ADMISS DENIALS	INV PROC ONLY DENIALS	INV PROC WAIVERS
* PROID 5MI00															
5MI00 8410	0	60	5	0	0	0	3	0	0	0	0	6	1	0	0
5MI00 8411	3	29	0	0	0	0	1	0	0	0	0	0	0	0	0
5MI00 8412	14	15	0	0	0	0	1	0	0	0	0	0	0	0	0
5MI00 8501	20	22	0	0	0	0	0	0	0	0	0	0	0	0	0
5MI00 8502	96	26	0	0	0	0	0	0	0	0	0	0	0	0	0
5MI00 8503	209	66	0	0	0	0	19	0	0	0	0	0	0	0	0
5MI00 8504	140	124	0	0	0	22	37	0	0	0	39	0	0	0	0
** SUBTOTAL **															
	482	342	5	0	0	22	61	0	0	0	39	6	1	0	0
* PROID 5MN00															
5MN00 8408	82	82	0	1	0	0	0	0	0	0	0	0	0	0	0
5MN00 8409	127	127	0	1	1	0	0	0	0	0	331	331	2	0	2
5MN00 8410	0	64	0	2	1	0	0	0	0	0	0	0	4	0	0
5MN00 8411	70	60	0	0	0	0	3	0	0	0	188	424	1	0	0
5MN00 8412	91	88	0	1	0	2	3	0	0	0	137	402	0	0	0
5MN00 8501	55	99	0	0	0	0	1	0	0	0	193	402	4	0	2
5MN00 8502	94	63	0	0	0	0	0	0	0	0	142	367	2	0	0
5MN00 8503	103	56	0	0	0	0	0	0	0	0	354	379	0	0	0
5MN00 8504	101	147	0	2	0	0	3	0	0	0	345	372	2	0	0
** SUBTOTAL **															
	723	786	0	7	2	2	10	0	0	0	1690	2677	15	0	4
* PROID 5OH00															
5OH00 8410	87	122	0	0	0	2	2	0	0	0	0	0	0	0	0
5OH00 8411	128	43	0	0	0	3	4	0	0	0	0	0	0	0	0
5OH00 8412	188	171	0	0	0	0	4	0	0	0	0	0	0	0	0
5OH00 8501	163	210	0	0	0	0	5	0	0	0	115	115	0	0	0
5OH00 8502	223	199	0	0	0	6	9	0	0	0	558	390	0	0	0
5OH00 8503	293	252	0	0	0	9	9	0	0	0	572	434	0	0	0
5OH00 8504	465	439	0	0	0	1	3	0	0	0	1607	1163	4	0	0
** SUBTOTAL **															
	1547	1436	0	0	0	21	36	0	0	0	2852	2102	4	0	0
* PROID 5WI00															
5WI00 8407	46	32	0	0	0	10	12	0	0	0	0	0	0	0	0
5WI00 8408	122	118	0	0	0	16	21	0	0	0	0	0	0	0	0
5WI00 8409	45	28	0	0	0	1	2	0	0	0	0	0	0	0	0
5WI00 8410	163	27	0	0	0	26	2	0	0	0	0	0	0	0	0
5WI00 8411	140	95	0	0	0	20	7	0	0	0	0	0	0	0	0
5WI00 8412	217	92	0	0	0	31	9	0	0	0	0	0	0	0	0

PRO MEDICAL REVIEW
PROCEDURE REVIEW
ACTIVITY REPORT

PROID YY/MM	PACE INSERT IDENT	PACE INSERT COMP	PACE INSERT ADMISS DENIAL	PACE INSERT PROC DENIAL	PACE INSERT WAIVER	PACE REIMP IDENT	PACE REIMP COMP	PACE REIMP ADMISS DENIAL	PACE REIMP PROC DENIAL	PACE REIMP WAIVER	INV PROC IDENT	INV PROC COMP	INV PROC ADMISS DENIALS	INV PROC ONLY DENIALS	INV PROC WAIVERS
* PROID 5WI00															
5WI00 8501	168	26	0	0	0	24	5	0	0	0	24	4	0	0	2
5WI00 8502	41	62	0	0	0	10	3	0	0	0	5	7	0	0	2
5WI00 8503	99	118	0	0	0	12	22	0	0	0	15	28	1	0	1
5WI00 8504	141	126	0	0	0	15	17	0	0	0	19	24	0	0	2
** SUBTOTAL **	1182	724	0	0	0	165	100	0	0	0	63	63	1	0	1
* PROID 6AR00 We leave July	33	7	?	1	0	5	0	0	0	0					
6AR00 8408	11	11	0	2	0	0	0	0	0	0	0	0	0	0	0
6AR00 8409	75	61	0	12	0	3	1	0	0	0	0	0	0	0	0
6AR00 8410	67	74	0	5	0	1	2	0	0	0	0	0	0	0	0
6AR00 8411	63	42	0	7	7	9	2	2	2	2	0	0	0	0	0
6AR00 8412	78	60	0	4	4	12	7	0	0	0	0	0	0	0	0
6AR00 8501	51	66	2	7	8	1	11	0	0	0	0	0	0	0	0
6AR00 8502	41	35	0	3	3	12	1	0	0	0	0	0	0	0	0
6AR00 8503	58	58	0	5	3	1	12	0	0	0	0	0	0	0	0
6AR00 8504	50	61	0	6	4	12	5	0	0	0	0	0	0	0	0
** SUBTOTAL **	494	468	2	51	29	51	41	2	2	2	0	0	0	0	0
* PROID 6LA00															
6LA00 8408	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0
6LA00 8409	66	66	0	0	0	0	0	0	0	0	0	0	0	0	0
6LA00 8410	0	21	0	0	0	0	0	0	0	0	0	0	0	0	0
6LA00 8411	0	12	0	0	0	0	0	0	0	0	0	0	0	0	0
6LA00 8412	80	35	0	0	0	0	0	0	0	0	0	0	0	0	0
6LA00 8501	201	30	0	0	0	0	0	0	0	0	58	14	0	1	1
6LA00 8502	53	55	0	0	0	0	0	0	0	0	27	11	0	0	0
6LA00 8503	0	90	0	0	0	0	0	0	0	0	0	31	0	0	0
6LA00 8504	59	106	1	1	1	0	0	0	0	0	11	19	0	0	0
** SUBTOTAL **	461	425	1	1	1	0	0	0	0	0	96	75	0	1	1
* PROID 6NM00															
6NM00 8408	4	1	0	0	0	0	1	0	0	0	0	0	0	0	0
6NM00 8409	18	0	0	0	0	0	0	0	0	0	0	0	0	0	0
6NM00 8410	16	0 1	0	0	0	0	0	0	0	0	0	0	0	0	0
6NM00 8411	11	13	0	0	0	0	1	0	0	0	0	0	0	0	0
6NM00 8412	13	10	0	0	0	0	0	0	0	0	0	0	0	0	0
6NM00 8501	31	12	0	0	0	0	0	0	0	0	0	0	0	0	0
6NM00 8502	11	5	0	0	0	0	0	0	0	0	0	0	0	0	0

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PROID YY/MM	PACE INSERT IDENT	PACE INSERT COMP	PACE INSERT ADMISS DENIAL	PACE INSERT PROC DENIAL	PACE INSERT WAIVER	PACE REIMP IDENT	PACE REIMP COMP	PACE REIMP ADMISS DENIAL	PACE REIMP PROC DENIAL	PACE REIMP WAIVER	INV PROC IDENT	INV PROC COMP	INV PROC ADMISS DENIALS	INV PROC ONLY DENIALS	INV PROC WAIVER
* PROID 6NM00															
6NM00 8503	19	5	0	0	0	0	0	0	0	0	0	0	0	0	
6NM00 8504	3	14	0	0	0	0	2	0	0	0	0	0	0	0	
** SUBTOTAL **	126	60	0	0	0	0	4	0	0	0	0	0	0	0	
* PROID 6OK00															
6OK00 8410	110	165	1	0	0	0	22	0	0	0	98	105	0	0	
6OK00 8411	108	135	1	0	0	0	12	0	0	0	114	117	0	0	
6OK00 8412	93	78	0	0	0	0	17	0	0	0	406	65	4	0	
6OK00 8501	111	69	0	0	0	16	10	0	0	0	1019	10	0	0	
6OK00 8502	88	65	0	0	0	14	3	0	0	0	942	222	1	0	
6OK00 8503	121	115	0	0	0	25	17	0	0	0	1171	1100	2	0	
6OK00 8504	121	78	0	0	0	25	15	0	0	0	1171	936	16	0	1
** SUBTOTAL **	752	705	2	0	0	80	96	0	0	0	4921	2555	23	0	1
* PROID 6TX00															
6TX00 8410	0	29	1	0	0	0	0	0	0	0	0	0	0	0	
6TX00 8411	1	1	0	0	0	0	0	0	0	0	0	0	0	0	
6TX00 8412	29	31	0	3	0	0	0	0	0	0	0	0	0	0	
6TX00 8501	63	55	0	0	0	0	0	0	0	0	0	0	0	0	
6TX00 8502	28	24	0	0	0	0	0	0	0	0	0	0	0	0	
6TX00 8503	100	100	2	2	0	15	15	1	0	0	0	0	0	0	
6TX00 8504	70	70	1	1	0	4	4	0	0	0	0	0	0	0	
** SUBTOTAL **	291	310	4	6	0	19	19	1	0	0	0	0	0	0	
* PROID 7IA00															
7IA00 8407	37	37	0	0	0	0	0	0	0	0	262	262	0	0	
7IA00 8408	63	63	0	0	0	0	0	0	0	0	711	711	7	2	
7IA00 8409	74	74	0	4	0	0	0	0	0	0	865	865	7	3	
7IA00 8410	49	49	0	1	0	3	3	0	0	0	696	696	12	6	
7IA00 8411	74	74	0	4	0	0	0	0	0	0	808	808	2	4	
7IA00 8412	43	43	0	1	0	2	2	0	0	0	447	447	0	4	
7IA00 8501	72	72	0	0	0	1	1	0	0	0	802	802	5	4	
7IA00 8502	60	60	0	1	0	0	0	0	0	0	527	527	4	4	
7IA00 8503	58	58	0	1	0	0	0	0	0	0	534	534	7	9	
7IA00 8504	72	72	0	1	0	0	0	0	0	0	495	495	0	2	
** SUBTOTAL **	602	602	0	13	0	6	6	0	0	0	6147	6147	44	38	

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PROID YY/MM	PACE INSERT IDENT	PACE INSERT COMP	PACE INSERT ADMISS DENIAL	PACE INSERT PROC DENIAL	PACE INSERT WAIVER	PACE REIMP IDENT	PACE REIMP COMP	PACE REIMP ADMISS DENIAL	PACE REIMP PROC DENIAL	PACE REIMP WAIVER	INV PROC IDENT	INV PROC COMP	INV PROC ADMISS DENIALS	INV PROC ONLY DENIALS	INV PRO WAIVE
* PROID 7KS00															
7KS00 8407	33	33	0	0	0	0	0	0	0	0	51	51	0	1	
7KS00 8408	14	14	0	0	0	2	2	0	0	0	7	7	0	0	
7KS00 8409	34	33	0	0	0	2	2	0	0	0	0	0	0	0	
7KS00 8410	16	12	0	0	0	0	0	0	0	0	0	1	0	0	
7KS00 8411	19	34	0	0	0	5	2	0	0	0	0	8	0	0	
7KS00 8412	72	0	0	0	0	5	0	0	0	0	0	0	0	0	
7KS00 8501	27	6	0	0	0	0	0	0	0	0	0	0	0	0	
7KS00 8502	42	1	0	0	0	2	0	0	0	0	0	0	0	0	
7KS00 8503	44	32	0	0	0	2	0	0	0	0	0	0	0	0	
7KS00 8504	50	45	0	3	3	2	1	0	0	0	0	0	0	0	
** SUBTOTAL **	351	210	0	3	3	20	7	0	0	0	58	67	0	1	
* PROID 7MO00															
7MO00 8408	73	27	0	0	0	9	2	0	0	0	0	0	0	0	
7MO00 8409	71	71	0	0	0	17	16	0	0	0	0	0	0	0	
7MO00 8410	96	96	0	0	0	18	18	0	0	0	15	15	0	0	
7MO00 8411	88	75	0	0	0	27	23	0	0	0	0	0	0	0	
7MO00 8412	123	116	0	0	0	41	33	0	0	0	0	0	0	0	
7MO00 8501	112	113	0	0	0	34	42	1	0	0	0	0	0	0	
7MO00 8502	70	36	0	0	0	18	10	0	0	0	0	0	0	0	
7MO00 8503	136	95	0	0	0	13	9	0	0	0	0	0	0	0	
7MO00 8504	128	131	0	0	0	39	31	0	0	0	0	0	0	0	
** SUBTOTAL **	897	760	0	0	0	216	184	1	0	0	15	15	0	0	0
* PROID 7NE00															
7NE00 8410	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7NE00 8411	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7NE00 8412	59	0	0	0	0	5	0	0	0	0	0	0	0	0	0
7NE00 8501	46	10	0	0	0	0	0	0	0	0	0	0	0	0	0
7NE00 8502	0	5	0	0	0	0	0	0	0	0	0	0	0	0	0
7NE00 8503	46	17	0	0	0	0	0	0	0	0	0	0	0	0	0
7NE00 8504	28	12	0	0	0	0	0	0	0	0	0	0	0	0	0
** SUBTOTAL **	179	44	0	0	0	5	0	0	0	0	0	0	0	0	0
* PROID 8CO00															
8CO00 8408	48	38	0	1	0	7	6	0	0	0	0	0	0	0	0
8CO00 8409	36	41	0	0	0	0	0	0	0	0	0	0	0	0	0
8CO00 8410	31	33	0	0	0	3	3	0	0	0	0	0	0	0	0

PRO MEDICAL REVIEW
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PROID YY/MM	PACE INSERT IDENT	PACE INSERT COMP	PACE INSERT ADMISS DENIAL	PACE INSERT PROC DENIAL	PACE INSERT WAIVER	PACE REIMP IDENT	PACE REIMP COMP	PACE REIMP ADMISS DENIAL	PACE REIMP PROC DENIAL	PACE REIMP WAIVER	INV PROC IDENT	INV PROC COMP	INV PROC ADMISS DENIALS	INV PROC ONLY DENIALS	INV PROC WAIVER
* PROID 8CO00															
8CO00 8411	30	30	0	0	0	2	2	0	0	0	0	0	0	0	
8CO00 8412	18	27	0	0	0	1	1	0	0	0	0	0	0	0	
8CO00 8501	12	11	0	0	0	1	1	0	0	0	22	0	0	0	
8CO00 8502	44	40	0	0	0	2	2	0	0	0	248	242	1	0	
8CO00 8503	20	20	1	0	1	1	1	0	0	0	148	161	10	0	
8CO00 8504	31	36	0	0	0	0	0	0	0	0	208	212	3	0	1
** SUBTOTAL **	270	276	1	1	1	17	16	0	0	0	626	615	14	0	1
* PROID 8MT00															
8MT00 8407	4	4	0	0	0	0	0	0	0	0	4	0	0	0	0
8MT00 8408	4	4	0	0	0	0	0	0	0	0	4	3	0	0	0
8MT00 8409	6	6	0	0	0	0	0	0	0	0	22	6	0	0	0
8MT00 8410	6	2	0	0	0	0	0	0	0	0	8	0	0	0	0
8MT00 8411	4	3	0	0	0	0	0	0	0	0	242	103	0	0	0
8MT00 8412	26	8	0	0	0	0	0	0	0	0	297	71	0	0	0
8MT00 8501	28	9	0	0	0	0	0	0	0	0	206	134	0	0	0
8MT00 8502	14	32	0	0	0	0	0	0	0	0	119	185	0	0	0
8MT00 8503	33	11	0	0	0	0	0	0	0	0	358	139	0	0	0
8MT00 8504	19	23	0	0	0	0	0	0	0	0	194	299	0	0	0
** SUBTOTAL **	144	102	0	0	0	0	0	0	0	0	1454	948	0	0	0
* PROID 8ND00															
8ND00 8408	13	4	0	0	0	2	0	0	0	0	0	0	0	0	0
8ND00 8409	8	8	0	0	0	0	6	0	0	0	0	0	0	0	0
8ND00 8410	0	5	0	0	0	1	0	0	0	0	0	0	0	0	0
8ND00 8411	6	0	0	0	0	0	0	0	0	0	89	0	0	0	0
8ND00 8412	18	4	0	0	0	1	0	0	0	0	483	98	0	0	0
8ND00 8501	10	12	0	0	0	3	1	0	0	0	279	381	0	0	0
8ND00 8502	21	7	0	0	0	1	3	0	0	0	377	216	0	0	0
8ND00 8503	14	14	0	0	0	4	1	0	0	0	314	254	0	0	0
8ND00 8504	15	15	0	0	0	2	5	0	0	0	341	304	0	0	0
** SUBTOTAL **	105	69	0	0	0	14	16	0	0	0	1883	1253	0	0	0
* PROID 8SD00															
8SD00 8410	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8SD00 8411	12	15	0	0	0	1	1	0	0	0	1	0	0	0	0
8SD00 8412	16	16	0	0	0	1	1	0	0	0	2	2	1	0	1
8SD00 8501	22	3	0	0	0	0	0	0	0	0	8	3	0	0	0

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PROID YY/MM	PACE INSERT IDENT	PACE INSERT COMP	PACE INSERT ADMISS DENIAL	PACE INSERT PROC DENIAL	PACE INSERT WAIVER	PACE REIMP IDENT	PACE REIMP COMP	PACE REIMP ADMISS DENIAL	PACE REIMP PROC DENIAL	PACE REIMP WAIVER	INV PROC IDENT	INV PROC COMP	INV PROC ADMISS DENIALS	INV PROC ONLY DENIALS	INV PROC WAIVERS
* PROID 8SD00															
8SD00 8502	11	7	0	0	0	0	0	0	0	0	4	3	0	0	0
8SD00 8503	12	5	0	0	0	0	2	0	0	0	4	3	1	0	1
8SD00 8504	19	16	0	0	0	0	0	0	0	0	4	1	1	0	0
** SUBTOTAL **															
	92	62	0	0	0	2	4	0	0	0	23	12	3	0	2
* PROID 8UT00															
8UT00 8407	6	6	0	0	0	2	2	0	0	0	0	0	0	0	0
8UT00 8408	0	11	0	0	0	0	1	0	0	0	0	0	0	0	0
8UT00 8409	22	22	0	0	0	4	4	0	0	0	0	0	0	0	0
8UT00 8410	10	10	0	0	0	1	1	0	0	0	0	0	0	0	0
8UT00 8411	77	77	0	0	0	9	9	0	0	0	167	167	0	0	0
8UT00 8412	18	41	0	0	0	7	8	0	0	0	54	60	0	0	0
8UT00 8501	13	23	0	0	0	0	0	0	0	0	81	96	0	0	0
8UT00 8502	23	13	0	0	0	1	2	0	0	0	68	74	0	0	0
8UT00 8503	6	20	0	0	0	3	5	0	0	0	61	105	0	0	0
8UT00 8504	45	7	0	0	0	3	5	0	0	0	11	37	0	0	0
** SUBTOTAL **															
	220	230	0	0	0	30	37	0	0	0	442	539	0	0	0
* PROID 8WY00															
8WY00 8407	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8WY00 8408	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8WY00 8409	4	0	0	0	0	0	0	0	0	0	17	0	0	0	0
8WY00 8410	5	1	0	0	0	0	0	0	0	0	23	5	0	0	0
8WY00 8411	1	2	0	0	0	0	0	0	0	0	21	54	0	0	0
8WY00 8412	3	1	0	0	0	① 0	0	0	0	0	85	14	0	0	0
8WY00 8501	9	2	0	0	0	0	0	0	0	0	97	92	0	0	0
8WY00 8502	12	5	0	0	0	⓪ 1	0	0	0	0	96	92	0	0	0
8WY00 8503	2	4	0	0	0	0	0	0	0	0	48	23	0	0	0
8WY00 8504	4	1	0	0	0	0	0	0	0	0	33	37	0	0	0
** SUBTOTAL **															
	40	16	0	0	0	1	0	0	0	0	420	317	0	0	0
* PROID 9AZ00															
9AZ00 8408	0	40	0	0	0	0	2	0	0	0	0	0	0	0	0
9AZ00 8409	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0
9AZ00 8410	14	[illegible] ⑮	0	0	0	0	2⑦	0	0	0	517	0	0	0	0
9AZ00 8411	15	1②	0	0	0	0	2[illegible]	0	0	0	672	24	4	0	0
9AZ00 8412	5	3⑦	0	0	0	0	3②	0	0	0	675	84	11	0	0
9AZ00 8501	71	36	0	0	0	8	12[illegible]	0	0	0	334	411	57	0	0

PRO MEDICAL REVIEW
PROCEDURE REVIEW
ACTIVITY REPORT

PROID YY/MM	PACE INSERT IDENT	PACE INSERT COMP	PACE INSERT ADMISS DENIAL	PACE INSERT PROC DENIAL	PACE INSERT WAIVER	PACE REIMP IDENT	PACE REIMP COMP	PACE REIMP ADMISS DENIAL	PACE REIMP PROC DENIAL	PACE REIMP WAIVER	INV PROC IDENT	INV PROC COMP	INV PROC ADMISS DENIALS	INV PROC ONLY DENIALS	INV PROC WAIVER
* PROID 9AZ00															
9AZ00 8502	74	25 15	0	0	0	4	4	0	0	0	154	259	22	0	
9AZ00 8503	20	15	0	0	0	1	4	0	0	0	342	150	14	0	
9AZ00 8504	0	62	0	0	0	0	0	0	0	0	660	654	18	2	
** SUBTOTAL **	199	203	0	0	0	13	29	0	0	0	3354	1582	126	2	
* PROID 9CA00															
9CA00 8410	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
9CA00 8411	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
9CA00 8412	595	71	2	0	0	127	16	0	0	0	0	0	0	0	
9CA00 8501	367	230	0	0	0	70	65	0	0	0	0	0	0	0	
9CA00 8502	702	920	663	10	1	154	72	0	0	1	0	0	0	0	
9CA00 8503	361	326	1	0	1	75	52	0	0	0	0	0	0	0	
9CA00 8504	1024	619	4	6	4	221	130	0	0	0	0	0	0	0	
** SUBTOTAL **	3049	2166	7	16	6	647	335	0	0	1	0	0	0	0	
* PROID 9HI00															
9HI00 8411	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
9HI00 8412	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
9HI00 8501	0	1	0	0	0	0	0	0	0	0	79	79	16	0	
9HI00 8502	1	1	0	0	0	0	0	0	0	0	0	0	0	0	
9HI00 8503	19	0	0	0	0	0	0	0	0	0	0	0	0	0	
** SUBTOTAL **	20	2	0	0	0	0	0	0	0	0	79	79	16	0	
* PROID 9NV00															
9NV00 8407	12	12	0	1	0	0	0	0	0	0	0	0	0	0	
9NV00 8408	10	10	0	0	0	3	3	0	0	0	0	0	0	0	
9NV00 8409	11	11	0	0	0	3	3	0	0	0	0	0	0	0	
9NV00 8410	6	6	0	0	0	0	0	0	0	0	0	0	0	0	
9NV00 8411	6	6	0	0	0	1	1	0	0	0	0	0	0	0	
9NV00 8412	6	6	0	0	0	0	0	0	0	0	0	0	0	0	
9NV00 8501	6	6	0	0	0	1	1	0	0	0	0	0	0	0	
9NV00 8502	3	3	0	0	0	0	0	0	0	0	0	0	0	0	
9NV00 8503	0	3	0	0	0	1	1	0	0	0	0	0	0	0	
9NV00 8504	27	15	0	0	0	5	0	0	0	0	1368	618	37	0	26
** SUBTOTAL **	87	78	0	1	0	14	9	0	0	0	1368	618	37	0	26
** TOTAL **	24666	20743	101	124	112	2161	1927	20	3	4	71904	59147	1455	57	831

medicare
Carriers Manual
Part 3 - Claims Process

Department of Health
and Human Services

Heath Care Financing
Administration

Transmittal No. 968

Date March 1983

NEW MATERIAL	PAGE NO.	REPLACED PAGES
Coverage Issues Appendix Sec. 65-4-65-8	5 pp.	2 pp.

NEW POLICY—EFFECTIVE FOR SERVICES RENDERED ON OR AFTER: March 16, 1983

Section 65-6, Cardiac Pacemakers.—This section has been completely revised, and now includes indications for determining the medical necessity of permanent, implanted cardiac pacemakers under Medicare. This section delineates three groups of conditions for which pacemakers have generally been implanted and establishes coverage indications for each. These indications represent an initial step in a series of proposed revisions to Medicare's coverage of such devices. We expect to revise these instructions as additional information on medical indications for pacemaker implants becomes available. We also intend to add specific medical indications for the coverage of newer, more sophisticated cardiac pacemakers.

The Medicare regulations reference is 42 CFR 405.310(k).

gland and would be covered as a prosthetic device in the rare case when it is used in the treatment of "dry eye."

Cross-refer: HCFA-Pub. 13-3, SS 3110.4, 3110.5; HCFA-Pub. 14-3, SS 2130, 2133;
HCFA-Pub. 10, SS 210.4, 211

65-4 CAROTID SINUS NERVE STIMULATOR

Implantation of the carotid sinus nerve stimulator is indicated for relief of angina pectoris in carefully selected patients who are refractory to medical therapy and who after undergoing coronary angiography study either are poor candidates for or refuse to have coronary bypass surgery. In such cases, Medicare reimbursement may be made for this device and for the related services required for its implantation.

However, the use of the carotid sinus nerve stimulator in the treatment of paroxysmal supraventricular tachycardia is considered investigational and is not in common use by the medical community. The device and related services in such cases cannot be considered as reasonable and necessary for the treatment of an illness or injury or to improve the functioning of a malformed body member as required by S 1862(a)(1) of the law.

Cross-refer: HCFA-Pub. 13-3,S 3110.4; HCFA-Pub. 14-3, S 2130; HCFA-Pub. 10, SS 210.4, 211

65-5 ELECTRONIC SPEECH AIDS

Electronic speech aids are covered under Part B as prosthetic devices when the patient has had a laryngectomy or his larynx is permanently inoperative. There are two types of speech aids. One operates by placing a vibrating head against the throat; the other amplifies sound waves through a tube which is inserted into the user's mouth. A patient who has had radical neck surgery and/or extensive radiation to the anterior part of the neck would generally be able to use only the "oral tube" model or one of the more sensitive and more expensive "throat contact" devices.

Cross-refer: HCFA-Pub. 13-3, SS 3110.4; HCFA-Pub. 14-3, S 2130; HCFA-Pub. 10, S 228.4

65-6 CARDIAC PACEMAKERS—EFFECTIVE FOR SERVICES RENDERED ON OR AFTER March 16, 1983

Cardiac pacemakers are covered as prosthetic devices under the Medicare program, subject to the conditions and limitations described in this section. While cardiac pacemakers have been covered under Medicare for many years, to date there have been no specific guidelines for their implantation other than the general Medicare requirement that covered services be reasonable and necessary for the treatment of the condition. Beginning with services rendered on or after the effective date of this instruction all claims for pacemaker implantations are subject to the guidelines of this section.

These guidelines are based on certain assumptions regarding the clinical goals of pacemaker implantation. While some uses of pacemakers represent relatively certain or unambiguous usage, many others require considerable expertise and judgment.

Consequently, the medical necessity for pacemaker implantation must be viewed in the context of the overall management of the particular patient. The appropriateness of such implants may be conditional on other diagnostic or therapeutic modalities having been undertaken. Although significant complications and adverse side effects of pacemakers are relatively rare, they cannot be ignored when considering the use of pacemakers for dubious medical indications, or marginal clinical benefit.

These guidelines represent current medical indications for pacemaker implantation. As with other areas of medicine, advances in knowledge and techniques in cardiology are expected. Consequently, judgments about the medical necessity and acceptability of pacemaker implants can be expected to change. This instruction is, therefore, an initial one, and is expected to be modified as more information becomes available.

It should be noted that this instruction applies only to permanent, implanted pacemakers, and does not address the use of temporary, nonimplanted pacemakers.

The three groups of conditions outlined below deal with the necessity for cardiac pacemaker implants for patients in general. These are intended as guidelines for Medicare contractors to use in assessing the medical necessity of claims for pacemaker implantation. As with other guidelines, final coverage determinations must take account of the circumstances of the particular claim, as well as factors such as the medical history of the individual patient. However, as a general rule, contractors may view the three groups of medical indications below as representing, Group I: conditions under which pacemaker claims may be considered covered without further claims development; Group II: conditions which require more specific claims information, especially evidence of the patient's condition being chronic, rather than episodic, in order to assure coverage; and Group III: conditions which would generally result in denial, unless further claims development shows that they fall into one of the first two categories, or special medical circumstances exist sufficient to convince the contractor that the claim should be paid.

GROUP I: Conditions under which implantation of a cardiac pacemaker is generally considered acceptable or necessary, provided that the conditions are chronic or recurrent and not due to transient causes such as acute myocardial infarction, drug toxicity, or electrolyte imbalance. (In cases where there is a rhythm disturbance, if the rhythm disturbance is chronic or recurrent, a single episode of a symptom such as syncope or seizure is adequate to establish medical necessity.)

1. Acquired complete (also referred to as third degree) AV heart block with symptoms (e.g., syncope, seizures, congestive heart failure, dizziness, confusion or limited exercise tolerance).

2. Congenital complete heart block with severe bradycardia (in relation to age), or significant physiological deficits or significant symptoms due to the bradycardia.

3. Second degree AV heart block (also referred to as AV block and heart block) of Mobitz Type II with symptoms attributable to intermittent complete heart block.

4. Second degree AV heart block of Mobitz Type I with significant symptoms due to hemodynamic instability associated with the heart block.

5. Sinus bradycardia associated with major symptoms (e.g., syncope, seizures, congestive heart failure); or substantial sinus bradycardia (heart rate less than 50) associated with dizziness or confusion. The correlation between symptoms and bradycardia must be documented, or the symptoms must be clearly attributable to the bradycardia rather than to some other cause.

6. In selected and few patients, sinus bradycardia of lesser severity (heart rate 50-59) with dizziness or confusion. The correlation between symptoms and bradycardia must be documented, or the symptoms must be clearly attributable to the bradycardia rather than to some other cause.

7. Sinus bradycardia which is the consequence of long-term necessary drug treatment for which there is no acceptable alternative, when accompanied by significant symptoms (e.g., syncope, seizures, congestive heart failure, dizziness or confusion). The correlation between symptoms and bradycardia must be documented, or the symptoms must be clearly attributable to the bradycardia rather than to some other cause.

8. Sinus node dysfunction with or without tachyarrhythmias or AV conduction block—i.e., the bradycardia-tachycardia syndrome, sino-atrial block, sinus arrest—when accompanied by significant symptoms (e.g., syncope, seizures, congestive heart failure, dizziness or confusion).

9. Sinus node dysfunction with or without symptoms when there are potentially life-threatening ventricular arrhythmias or tachycardia secondary to the bradycardia (e.g., numerous premature ventricular contractions, couplets, runs of premature ventricular contractions, or ventricular tachycardia).

10. Bradycardia associated with supraventricular tachycardia (e.g., atrial fibrillation, atrial flutter, or paroxysmal atrial tachycardia) with high degree AV block which is unresponsive to appropriate pharmacological management and when the bradycardia is associated with significant symptoms (e.g., syncope, seizures, congestive heart failure, dizziness or confusion).

11. The occasional patient with hypersensitive carotid sinus syndrome with syncope due to bradycardia and unresponsive to prophylactic medical measures.

GROUP II: Conditions under which implantation of a cardiac pacemaker may be found acceptable or necessary, provided that the medical history and prognosis of the patient involved can be documented and there is evidence that the pacemaker implantation will assist in the overall management of the patient. As with Group I, the conditions must be present chronically or recurrently, and not due to such transient causes as acute myocardial infarction, drug toxicity, or electrolyte imbalance. Contractors should review claims with a view toward identifying such factors in order to determine whether the particular claims would be covered or not.

1. Acquired complete (third degree) AV heart block without symptoms.

2. Congenital complete heart block of less severe bradycardia (in relation to age).

3. Bifascicular or trifascicular block accompanied by syncope which is attributed to transient complete heart block after other plausible causes of syncope have been reasonably excluded.

4. Prophylactic pacemaker use following recovery from acute myocardial infarction during which there was temporary complete (third degree) and/or Mobitz Type II second degree AV block.

5. Asymptomatic second degree AV block of Mobitz Type II.

6. Very substantial sinus bradycardia (heart rate less than 45) which is a consequence of long-term necessary drug treatment for which there is no acceptable alternative, when not accompanied by significant symptoms.

7. In patients with recurrent and refractory ventricular tachycardia, "overdrive pacing" (pacing above the basal rate) to prevent ventricular tachycardia.

GROUP III: Conditions which, although used by some physicians as bases for permanent pacemaker implantation, are considered unsupported by adequate evidence of benefit and therefore should not generally be considered appropriate uses for pacemakers in the absence of indications cited in the above two groups. Contractors should review claims for pacemakers with Group III indications with a view toward further claims development prior to denying the claim. The contractors should attempt, in further developing the claim, to determine whether the particular claim may actually meet the conditions of Groups I or II. In claims where this is not the case, or where such an event appears unlikely, the contractor may deny the claim.

1. Syncope of undetermined cause.

2. Sinus bradycardia without significant symptoms.

3. Sino-atrial block or sinus arrest without significant symptoms.

4. Prolonged R-R intervals with atrial fibrillation (without third degree AV block) or with other causes of transient ventricular pause.

5 Bradycardia during sleep.

6. Right bundle branch block with left axis deviation (and other forms of fascicular or bundle branch block) without syncope or other symptoms of intermittent AV block.

7. Asymptomatic second degree AV block of Mobitz Type I.

Cross refer: HCFA Pub. 13-3, SS3101.4,3110.4, HCFA Pub. 14-3, S2130; HCFA Pub. 10, SS210.4, 228.4.

65-7 INTRAOCULAR LENSES (IOL's)

An intraocular lens, or pseudophakos, is a hard artificial lens which may be implanted to replace the natural lens after cataract surgery. Intraocular lens implantation services, as well as the lens itself, may be covered if reasonable and necessary for the individual. Implantation services may include hospital, surgical, and other medical services, including pre-implantation ultrasound (A-scan) eye measurement of one or both eyes.

The Food and Drug Administration (FDA) has classified IOL's into the following four categories, any of which may be covered:

(1) Anterior chamber angle fixation lenses
(2) Iris fixation lenses
(3) Irido-capsular fixation lenses
(4) Posterior chamber lenses

Although the FDA still considers IOL's investigational, their coverage under Medicare is an exception to the general policy not to cover experimental or investigational items or services. The exception is made because the Congress, recognizing the widespread use of IOL's, directed the FDA to study them without interfering with their availability to patients.

Cross-refer: HCFA-Pub. 13-3, SS3110.4, 3151, 3157; HCFA-Pub.14-3, S2130; HCFA-Pub. 10, S228.4

65-8 ELECTRICAL NERVE STIMULATORS

Two general classifications of electrical nerve stimulators are employed to treat chronic intractable pain: peripheral nerve stimulators and central nervous system stimulators.

A. Peripheral Nerve Stimulators.—Payment may be made under the prosthetic devices benefit for the following types of peripheral nerve stimulators:

1. Transcutaneous Electrical Nerve Stimulator (TENS).—This stimulator is attached to the surface of the patient's skin over the peripheral nerve to be stimulated. It may be applied in a variety of settings—in the patient's home, a physician's office, or in an outpatient clinic.

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Hospital Manual

Department of Health
and Human Services

Health Care Financing
Administration

Transmittal No. 439 | Date MAY 1985

REVISED MATERIAL	REVISED PAGES	REPLACED PAGES
Coverage Issues Appendix CIA 65-6 - 65-8	7 pp.	5 pp.

CHANGE IN POLICY—Effective Date: For services performed on and after May 9, 1985

CIA 65-6, Cardiac Pacemakers. This section delineates two groups of conditions for which cardiac pacemakers have generally been implanted (both single- and dual-chamber pacemakers), and establishes coverage and noncoverage guidelines for each. We expect to periodically revise these instructions as pacemaker technology changes and additional information on medical guidelines for pacemaker implants becomes available.

gland and would be covered as a prosthetic device in the rare case when it is used in the treatment of "dry eye."

Cross-refer: HCFA-Pub. 13-3, SS 3110.4, 3110.5; HCFA-Pub. 14-3, SS 2130, 2133;
HCFA-Pub. 10, SS 210.4, 211

65-4 CAROTID SINUS NERVE STIMULATOR

Implantation of the carotid sinus nerve stimulator is indicated for relief of angina pectoris in carefully selected patients who are refractory to medical therapy and who after undergoing coronary angiography study either are poor candidates for or refuse to have coronary bypass surgery. In such cases, Medicare reimbursement may be made for this device and for the related services required for its implantation.

However, the use of the carotid sinus nerve stimulator in the treatment of paroxysmal supraventricular tachycardia is considered investigational and is not in common use by the medical community. The device and related services in such cases cannot be considered as reasonable and necessary for the treatment of an illness or injury or to improve the functioning of a malformed body member as required by S 1862(a)(1) of the law.

Cross-refer: HCFA-Pub. 13-3,S 3110.4; HCFA-Pub. 14-3, S 2130; HCFA-Pub. 10, SS 210.4, 211

65-5 ELECTRONIC SPEECH AIDS

Electronic speech aids are covered under Part B as prosthetic devices when the patient has had a laryngectomy or ~~his~~ larynx is permanently inoperative. There are two types of speech aids. One operates by placing a vibrating head against the throat; the other amplifies sound waves through a tube which is inserted into the user's mouth. A patient who has had radical neck surgery and/or extensive radiation to the anterior part of the neck would generally be able to use only the "oral tube" model or one of the more sensitive and more expensive "throat contact" devices.

Cross-refer: HCFA-Pub. 13-3, S 3110.4; HCFA-Pub. 14-3, S 2130; HCFA-Pub. 10, S 228.4

65-6 CARDIAC PACEMAKERS

Cardiac pacemakers are covered as prosthetic devices under the Medicare program, subject to the conditions and limitations described in this section. While cardiac pacemakers have been covered under Medicare for many years, until recently there have been no specific guidelines for their implantation other than the general Medicare requirement that covered services be reasonable and necessary for the treatment of the condition. Services rendered for pacemaker implantations on or after the effective dates of this instruction are subject to the guidelines of this section.

These guidelines are based on certain assumptions regarding the clinical goals of pacemaker implantation. While some uses of pacemakers represent relatively certain or unambiguous usage, many others require considerable expertise and judgment.

Consequently, the medical necessity for pacemaker implantation must be viewed in the context of the overall management of the particular patient. The appropriateness of such implants may be conditional on other diagnostic or therapeutic modalities having been undertaken. Although significant complications and adverse side effects of pacemakers are relatively rare, they cannot be ignored when considering the use of pacemakers for dubious medical conditions, or marginal clinical benefit.

These guidelines represent current concepts regarding medical circumstances in which pacemaker implantation may be appropriate or necessary. As with other areas of medicine, advances in knowledge and techniques in cardiology are expected. Consequently, judgments about the medical necessity and acceptability of pacemaker implants can be expected to change, and instructions modified as more information becomes available.

It should be noted that this instruction applies only to permanent, implanted pacemakers, and does not address the use of temporary, nonimplanted pacemakers.

The two groups of conditions outlined below deal with the necessity for cardiac pacemaker implants for patients in general. These are intended as guidelines for Medicare contractors to use in assessing the medical necessity of claims for pacemaker implantation. As with other guidelines, final coverage determinations must take account of the circumstances of the particular claim, as well as factors such as the medical history of the individual patient. However, as a general rule, contractors may view the two groups of current medical concepts below as representing:

Group I: Single-Chamber Cardiac Pacemakers--A) conditions under which single-chamber pacemaker claims may be considered covered without further claims development; and B) conditions under which single-chamber pacemaker claims would be denied unless further claims development shows that they fall into the covered category, or special medical circumstances exist sufficient to convince the contractor that the claim should be paid.

Group II. Dual-Chamber Cardiac Pacemakers—A) conditions under which dual-chamber pacemaker claims may be considered covered without further claims development, and B) conditions under which dual-chamber pacemaker claims would be denied unless further claims development shows that they fall into the covered categories for single-and dual-chamber pacemakers, or special medical circumstances exist sufficient to convince the contractor that the claim should be paid.

GROUP I: SINGLE-CHAMBER CARDIAC PACEMAKERS—Effective for services rendered on or after March 16, 1983.

A. COVERED

Conditions under which implantation of a cardiac pacemaker is generally considered acceptable or necessary, provided that the conditions are chronic or recurrent and not due to transient causes such as acute myocardial infarction, drug toxicity, or electrolyte imbalance. (In cases where there is a rhythm disturbance, if the rhythm disturbance is chronic or recurrent, a single episode of a symptom such as syncope or seizure is adequate to establish medical necessity.)

1. Acquired complete (also referred to as third degree) AV heart block.

2. Congenital complete heart block with severe bradycardia (in relation to age), or significant physiological deficits or significant symptoms due to the bradycardia.

3. Second degree AV heart block of Type II (i.e., no progressive prolongation of P-R interval prior to each blocked beat).

4. Second degree AV heart block of Type I (i.e., progressive prolongation of P-R interval prior to each blocked beat) with significant symptoms due to hemodynamic instability associated with the heart block.

5. Sinus bradycardia associated with major symptoms (e.g., syncope, seizures, congestive heart failure); or substantial sinus bradycardia (heart rate less than 50) associated with dizziness or confusion. The correlation between symptoms and bradycardia must be documented, or the symptoms must be clearly attributable to the bradycardia rather than to some other cause.

6. In selected and few patients, sinus bradycardia of lesser severity (heart rate 50-59) with dizziness or confusion. The correlation between symptoms and bradycardia must be documented, or the symptoms must be clearly attributable to the bradycardia rather than to some other cause.

7. Sinus bradycardia which is the consequence of long-term necessary drug treatment for which there is no acceptable alternative, when accompanied by significant symptoms (e.g., syncope, seizures, congestive heart failure, dizziness or confusion). The correlation between symptoms and bradycardia must be documented, or the symptoms must be clearly attributable to the bradycardia rather than to some other cause.

8. Sinus node dysfunction with or without tachyarrhythmias or AV conduction block—i.e., the bradycardia-tachycardia syndrome, sino-atrial block, sinus arrest—when accompanied by significant symptoms (e.g., syncope, seizures, congestive heart failure, dizziness or confusion).

9. Sinus node dysfunction with or without symptoms when there are potentially life-threatening ventricular arrhythmias or tachycardia secondary to the bradycardia (e.g., numerous premature ventricular contractions, couplets, runs of premature ventricular contractions, or ventricular tachycardia).

10. Bradycardia associated with supraventricular tachycardia (e.g., atrial fibrillation, atrial flutter, or paroxysmal atrial tachycardia) with high degree AV block which is unresponsive to appropriate pharmacological management and when the bradycardia is associated with significant symptoms (e.g., syncope, seizures, congestive heart failure, dizziness or confusion).

11. The occasional patient with hypersensitive carotid sinus syndrome with syncope due to bradycardia and unresponsive to prophylactic medical measures.

12. Bifascicular or trifascicular block accompanied by syncope which is attributed to transient complete heart block after other plausible causes of syncope have been reasonably excluded.

13. Prophylactic pacemaker use following recovery from acute myocardial infarction during which there was temporary complete (third degree) and/or Mobitz Type II second degree AV block in association with bundle branch block.

14. In patients with recurrent and refractory ventricular tachycardia, "overdrive pacing" (pacing above the basal rate) to prevent ventricular tachycardia.

Effective for services rendered on or after **May 9, 1985.**

15. Second degree AV heart block of Type I with the QRS complexes prolonged.

B. NOT COVERED--Additional claims development may be required.

Conditions which, although used by some physicians as bases for permanent pacemaker implantation, are considered unsupported by adequate evidence of benefit and therefore should not generally be considered appropriate uses for single-chamber pacemakers in the absence of indications cited above. Contractors should review claims for pacemakers with these indications to determine the need for further claims development prior to denying the claim. The object of such further development is to establish whether the particular claim actually meets the conditions in A. above. In claims where this is not the case or where such an event appears unlikely, the contractor may deny the claim.

1. Syncope of undetermined cause.

2. Sinus bradycardia without significant symptoms.

3. Sino-atrial block or sinus arrest without significant symptoms.

4. Prolonged R-R intervals with atrial fibrillation (without third degree AV block) or with other causes of transient ventricular pause.

5. Bradycardia during sleep.

6. Right bundle branch block with left axis deviation (and other forms of fascicular or bundle branch block) without syncope or other symptoms of intermittent AV block.

7. Asymptomatic second degree AV block of Type I unless the QRS complexes are prolonged or electrophysiological studies have demonstrated that the block is at or beyond the level of the His Bundle.

GROUP II: DUAL-CHAMBER CARDIAC PACEMAKERS—Effective for services rendered on or after **May 9, 1985.**

A. COVERED

Conditions under which implantation of a dual-chamber cardiac pacemaker is considered acceptable or necessary in the general medical community unless **conditions #1 and #2, Group II.B., are present :**

1. Patients in whom single-chamber (ventricular pacing) at the time of pacemaker insertion elicits a definite drop in blood pressure, retrograde conduction, or discomfort.

2. Patients in whom the pacemaker syndrome (atrial ventricular asynchrony), with significant symptoms, has already been experienced with a pacemaker that is being replaced.

3. Patients in whom even a relatively small increase in cardiac efficiency will importantly improve the quality of life, e.g., patients with congestive heart failure despite adequate other medical measures.

4. Patients in whom the pacemaker syndrome can be anticipated, e.g., in young and active people, etc.

Dual-chamber pacemakers may also be covered for the conditions, as listed in Group I.A. (Single-Chamber Cardiac Pacemakers), if the medical necessity is sufficiently justified through adequate claims development. Expert physicians differ in their judgments about what constitutes appropriate criteria for dual-chamber pacemaker use. The judgment that such a pacemaker is warranted in the patient meeting accepted criteria must be based upon the individual needs and characteristics of that patient, weighing the magnitude and likelihood of anticipated benefits against the magnitude and likelihood of disadvantages to the patient.

B. NOT COVERED

Whenever the following conditions (which represent overriding contraindications) are present, dual-chamber pacemakers are not covered:

1. Ineffective atrial contractions—e.g., chronic atrial fibrillation or flutter, or giant left atrium.

2. Frequent or persistent supraventricular tachycardias, except where the pacemaker is specifically for the control of the tachycardia.

3. A clinical condition in which pacing takes place only intermittently and briefly, and which is not associated with a reasonable likelihood that pacing needs will become prolonged, e.g., the occasional patient with hypersensitive carotid sinus syndrome with syncope due to bradycardia and unresponsive to prophylactic medical measures.

4. Prophylactic pacemaker use following recovery from acute myocardial infarction during which there was temporary complete (third degree) and/or Type II second degree AV block in association with bundle branch block.

Cross refer: HCFA Pub. 13-3, §§3101.4, 3110.4, HCFA Pub. 14-3, §2130; HCFA Pub. 10, §§210.4, 228.4.

PACE

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Edited by Graeme Sloman

THE NORTH AMERICAN SOCIETY OF PACING AND ELECTROPHYSIOLOGY

1

COMPARATIVE SURVIVAL FOLLOWING PERMANENT AV SEQUENTIAL VERSUS PERMANENT VENTRICULAR DEMAND PACING FOR SINUS NODE DYSFUNCTION IN PATIENTS WITH AND WITHOUT HEART FAILURE.

Martin Alpert, M.D., Jack Curtis, M.D., John Sanfelippo, M.D., Greg Flaker, M.D., University of Missouri School of Medicine, Columbia, MO.

To determine whether survival following permanent ventricular demand pacing differs from survival following permanent AV sequential pacing in patients with symptomatic sinus node dysfunction (unexplained sinus bradycardia, subsidiary rhythms, sinus arrest, sinoatrial block or the bradycardia/tachycardia syndrome), we followed 71 patients who received a VVI pacemaker (Group I) and 48 patients who received a DVI or DDD pacemaker (Group II) for 1-5 years. Pre-existent congestive heart failure (CHF) was present in 31% of Group I patients and 33% of Group II patients. There was no significant difference in sex distribution, mean age or the incidence of coronary heart disease, hypertension, valvular heart disease, diabetes mellitus, stroke or renal failure between Groups I and II. Overall, the predicted cumulative survival at one, three and five years was 90%, 83% and 76% respectively for Group I and 94%, 86% and 78% respectively for Group II. In patients with pre-existent CHF predicted cumulative survival at one, three and five years was 78%, 69% and 59% respectively for Group I and 90%, 83% and 75% respectively for Group II. Five year predicted cumulative survival was significantly lower in Group I patients with pre-existent CHF than in Group II patients with pre-existent CHF ($p < 0.03$). There was no significant difference in five year cumulative survival between Groups I and II in patients without pre-existent CHF. Thus, it appears that permanent AV sequential pacing enhances survival to a greater extent than permanent ventricular demand pacing in patients with chronic symptomatic sinus node dysfunction and pre-existent CHF.

2

PACEMAKER DEPENDENCY FOLLOWING CESSATION OF PACING

Michael Behrens, R.N., Peter Klementowicz, M.D, Cary Andrews, P.A.-C., Kalman Ausubel, M.D., Seymour Furman, M.D. Montefiore Medical Center, Bronx, New York

Pacemaker dependency (PD) can be defined as the risk of serious injury or death from sudden pacemaker (PM) failure, an event more dangerous than progressive rate decrease. 100 consecutive, recumbent, monitored pts were studied after sudden PM inhibition by chest wall stimulation to identify PD. The unpaced rhythm established 4 classes of PD: Class I - 5 seconds of asystole; Class II - 2 to 5 seconds of asystole with escape by complete heart block (CHB) with NSR or atrial fibrillation; Class III - escape by lesser degrees of AV block, ventricular ectopy, sinus bradycardia equal to or less than 30 bpm; Class IV - escape by NSR of 40 bpm or greater; Classes III and IV were deemed non-dependent (NPD). Frequency of the rhythm response was documented by chart review of all outpatient visits, 2-50 (18 ± 3) for Classes I and II and 2-42 (12 ± 1) for Classes III and IV. Pts were placed in the most PM dependent category ever recorded. Of 100, 23 were Class I, 33 Class II, 16 Class III and 28 Class IV. In Classes I and II, findings were repetitive with (17) always seen as tested. 56% (56/100) were sometimes seen in a PD state. 30% of the PD group (17/56) or 17% (17/100) of the whole were documented as being always PD. 68% (38/56) of Class I and II pts were asymptomatic during PM inhibition while 9% (4/44) of Class III and IV (NPD) pts were symptomatic at testing. All symptoms were non-specific. Worth noting is a pt who suffered cardiac arrest in the PM center as a result of a failing PM and coincidental CHB (undocumented in 18 prior follow-ups). In one visit he moved from Class IV to Class I. Insertion of a temporary PM and other resuscitative measures were required. In less than 24 hrs the pt had returned to and remains in NSR. While PD is comprised of many factors some only episodically present, by our criteria an identified majority of our pts are at risk should the PM fail abruptly. Provocative testing and recognition of response variability are essential safeguards against that consequence without reliance on subjective response or ECG reproducibility.

3

PREVALENCE OF INDICATED, UNWARRANTED AND UNDOCUMENTED PACEMAKER IMPLANTS IN PHILADELPHIA

Allan M. Greenspan, M.D., FACC, Harold R. Kay, M.D., FACC, Bruce C. Berger, M.D., FACC, Richard M. Greenberg, M.D., FACC, Arnold J. Greenspon, M.D., FACC, Susan Bosch, Beth Saunders, Mary Jane Spuhler Gaughan, Philadelphia PSRO, Phila., PA.

Indications for primary pacemaker implants (IMP) performed between Jan. and June, 1983 in 30 hospitals in Philadelphia County, PA were reviewed in 381 Medicare patients (pts) (93% of all IMP). Complete chart review included analysis of history, ECG, telemetry and ambulatory monitoring strips in a blinded fashion by an experienced panel of cardiac electrophysiologists, cardiologists, cardiac surgeons, nurses and medical record quality review specialists. Based on all available data IMP were classified into 3 groups: INDICATED (N=151, 40%), NOT INDICATED (N=59, 15%) and POSSIBLY INDICATED (N=171, 45%). Of 171 POSSIBLY INDICATED IMP, 59 (34%) had inadequate chart documentation and 112 (66%) required further diagnostic workup. When hospitals were subclassified by type (university, affiliate and community) or by annual number of IMP (<25, 25-49 and >=50) there was no difference in the number of not indicated IMP. We conclude from this large multi-hospital study, there may be a need for more critical evaluation and documentation of the indications for primary pacemaker implants.

4

SERIAL EXERCISE TOLERANCE TESTS IN PHYSIOLOGICALLY PACED PATIENTS

Takao Mitsuoka, M.D., Rose Anne Kenny, M.R.C.P.,
Tony Au Yeung, M.R.C.P., Siew Lu Chan, Rudolph Canepa-Anson, M.R.C.P, Richard Sutton, F.R.C.P.
Westminster Hospital, London, England.

Adaptation to the pacing modes DDD and VVI and training effects may influence the results of serial exercise stress tests. Fifteen patients, 7 with sick sinus syndrome (SSS) and 8 with atrioventricular block (AVB) completed a randomised double blind cross over study to compare exercise capacity immediately after pacemaker mode change (acute) and after a one month period in the mode (chronic). The results of maximal effort tolerance in kpm ± 1 SD for SSS in VVIa 3587 ± 1894, VVIc 3932 ± 2289, in DDDa 3641 ± 1899, in DDDc 4025 ± 2342, in AVB patients with VVIa 2398 ± 587, VVIc 2486 ± 467, DDDa 2827 ± 827, DDDc 3154 ± 612. All but one SSS patient developed sinus rhythm during exercise in both modes: one patient showed retrograde AV conduction in VVI tests only. There was no significant difference in serial tests in the same pacemaker mode either in SSS or AVB patients which indicates a lack of importance of training effect. However, DDD pacing in AVB patients was highly significantly (DDDc vs VVIc $P < 0.01$) better than VVI chronically emphasising the benefit of DDD pacing and showing the benefit may not be measurable on acute tests (DDDa vs VVIa P.N.S.) which is considered adaptation to the physiological mode.

BRIGHAM AND WOMEN'S HOSPITAL

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PHILIP J. PODRID, M.D.
STEVEN LAMPERT, M.D.
CHARLES M. BLATT, M.D.

May 10, 1985

The Honorable John Heinz
Chairman
Special Committee on Aging
United States Senate
G33 Dirksen Building
Washington, DC 20510

Dear Senator Heinz:

I apologize for the delay in responding to your letter of April 26th but, as I indicated to David Schulke, I had been out of the country and only now have had opportunity to reply. With regard to the specific questions posed:

1. The figure of 1.5% unnecessary pacemaker implantations, as judged by PRO utilization review, does not I believe reflect the actual number of inappropriate pacemaker implantations. Based on our group's experience with second opinions for pacemaker implants; our experience with explantation (removal) of pacing units in a number of patients and our working group's own recommendations as published in the Journal of the American Medical Association (JAMA), that figure of 1.5% is woefully low.

2. The Medicare guidelines for pacemaker implantation allow for a wide range of interpretation, particularly in the area of bradycardia (#s I5-7). There are elderly people who will exhibit heart rates in the 40's, feel perfectly well, yet experience some occasional dizziness unrelated to slow heart rate, and will be deemed candidates for pacemaker implantation. Group II categories are quite loose, particularly II-6. Again, many elderly people will be receiving medication for high blood pressure or angina pectoris which does slow the heart rate. There are physicians who will implant a pacemaker in anticipation of bradycardia which may or may not occur with those particular medications. Similarly, the New York STate Peer Review guidelines are questionably liberal; specifically conditions #5 & 7.

Our guidelines in JAMA can be summarized in two major categories:
A) Symptomatic advanced or complete AV block.
B) Symptomatic bradyarrhythmia not induced by drugs or concomitant metabolic abnormalities.

3. I am not aware of "hard data" which addresses overutilization of pacemakers other than the collective experience of individuals such as those in our working group organized by Brendan Phibbs.

4. There is categorically no scientific reason why the percent of dual-chambered pacemakers has risen from 5% to 24%. Only a small minority of patients require dual-chamber pacing. Furthermore, the complexities of those pacemakers with the attendant pacemaker-induced arrhythmias has created problems in management of patients only rarely encountered previously with single-chamber pacemakers.

My own bias is that if reimbursement were precisely the same for single and dual-chambered pacemakers, the implantation rate of these units would drop dramatically. Industry does an impressive "marketing job" on physicians, urging their use of these units (see enclosure).

The implications of the increasing use of these units will be further cost not only in terms of the surgical and cardiologic fee, but also in followup because of the so-called "pacemaker-mediated tachycardias."

5. As I understand from Mr. Schulke, reimbursement for the surgical fee is somewhere between $1,000-2,000 dollars for this procedure. Considering the fact that if I spend one hour examining and counseling a heart attack patient in our office for which Medicare may reimburse me $50-60, the fee paid for a one-hour relatively simple procedure is unconscionable.

6. The data presented on second opinions for coronary bypass surgery should be framed in the context of those patients with chronic stable symptoms, and not those individuals admitted to hospital with unstable angina, requriing urgent surgery. If we assume that 1/3 of the 60,000 Medicare patients fall into the "unstable" group and the remaining 40,000 are "stable" and thus suitable for mandatory second opinion, a conservative estimate of those individuals suitable for deferred or avoided operation would be 50%. This translates to a savings of approximately 500 million dollars. If we subtract the cost of our medical second opinion program (see Appendix I), the savings are still in the range of 430 million dollars.

APPENDIX I

Projected cost of Second Opinion Center

$1500 evaluation fees (three visits at 6 month intervals over first 18 months). This fee incorporates all testing.

1500 x 40,000 = $60 million
plus one hospitalization at conservative cost of $5000 for 10% of the medically followed patients over a two-year follow-up - 10% x 20,000 patients = 2000 x $5000 = $10 million

Conservative Cost of Second Opinion Program = 70 million dollars
Net Savings = 430 million dollars

I do hope this information is of help to you and the Committee. It was an honor to have provided testimony and I will be available to assist in any way you deem necessary.

Sincerely,

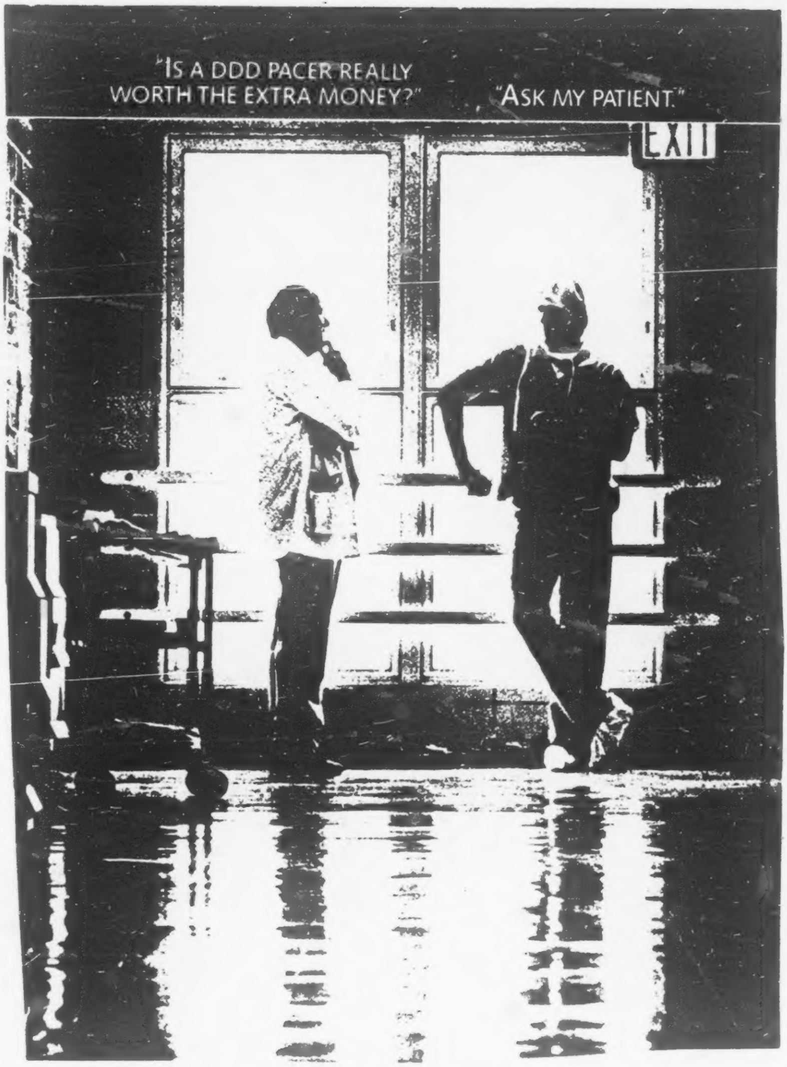
Thomas B. Graboys, M.D.
Director, Clinical Services
Cardiovascular Laboratories;
Assistant Professor of Medicine,
Harvard Medical School

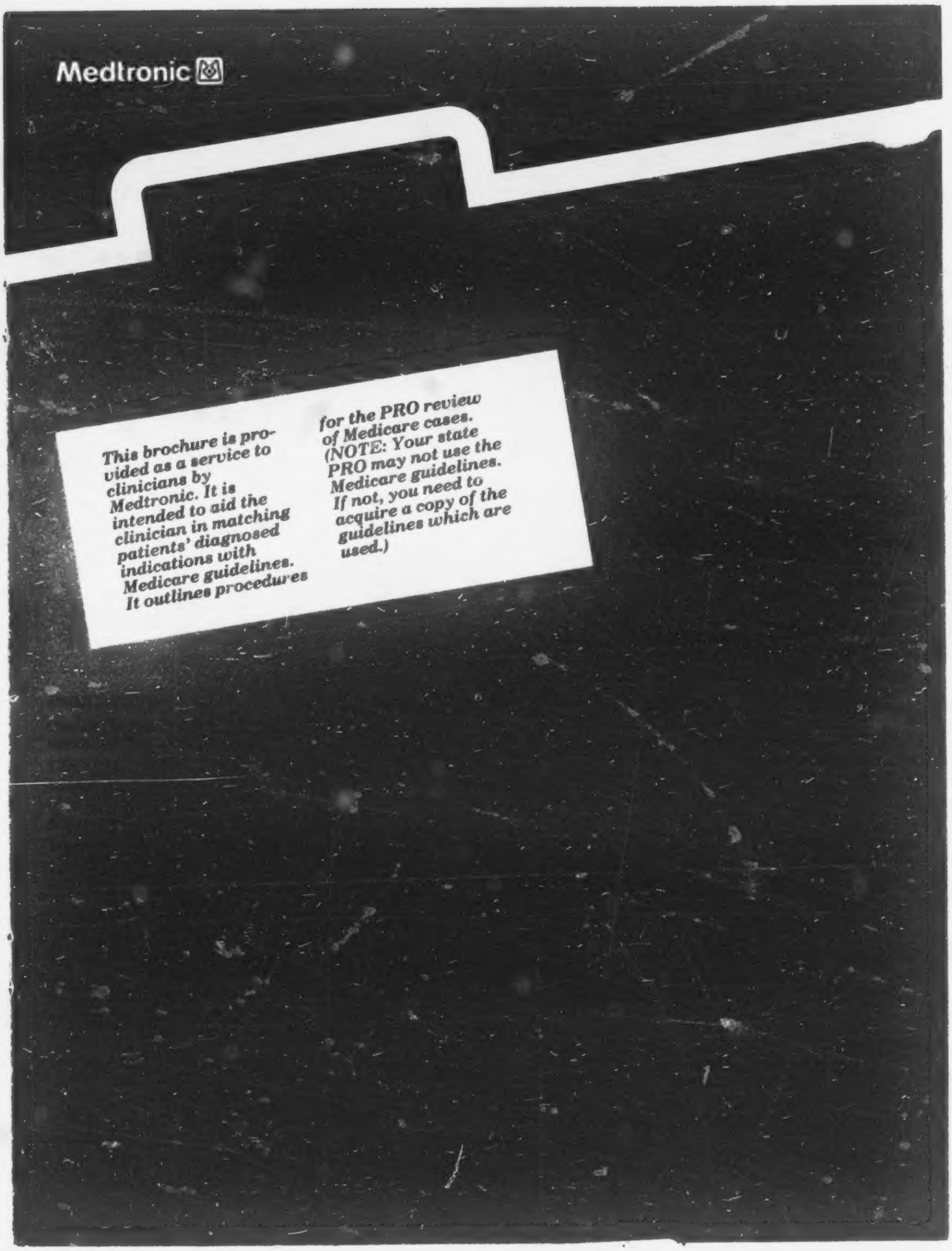
/cmk:1-3

enclosure

→ cc: David Schulke

Pacemaker Co.
Advert.
1985

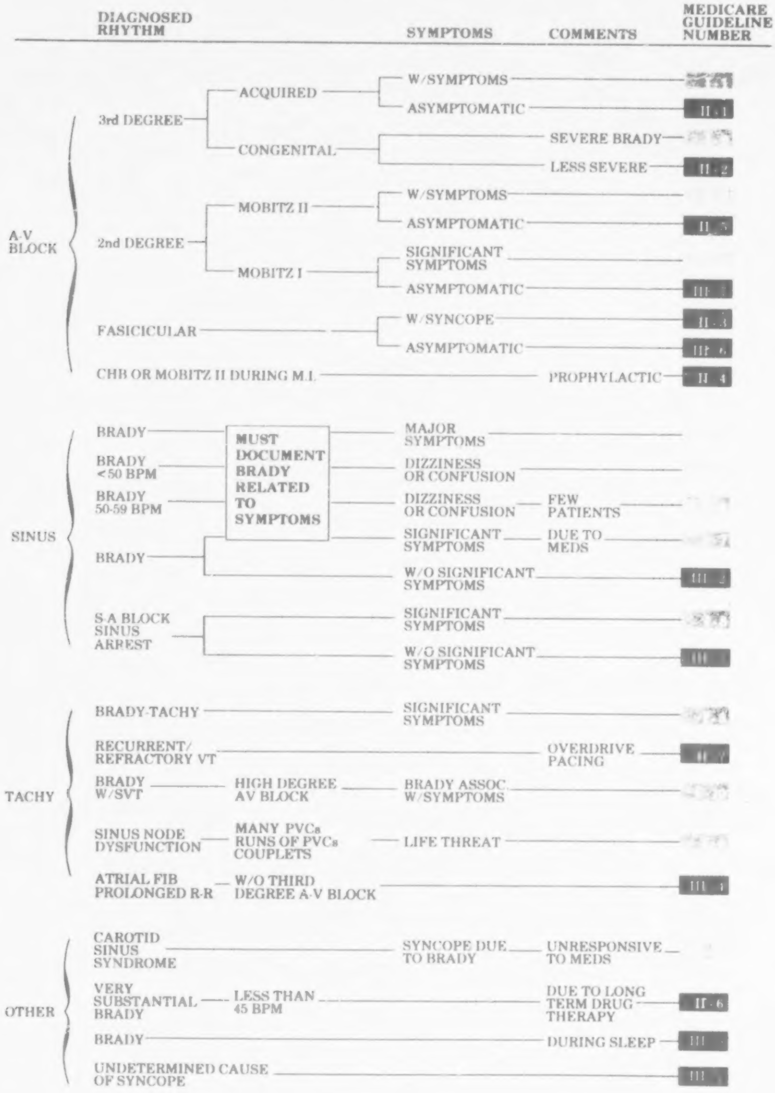

"IS A DDD PACER REALLY WORTH THE EXTRA MONEY?"
"ASK MY PATIENT."
EXIT



Medtronic

This brochure is provided as a service to clinicians by Medtronic. It is intended to aid the clinician in matching patients' diagnosed indications with Medicare guidelines. It outlines procedures for the PRO review of Medicare cases. (NOTE: Your state PRO may not use the Medicare guidelines. If not, you need to acquire a copy of the guidelines which are used.)

This diagram is for use solely as a guide to find the proper category in the published Medicare Indications for pacing (p.3). It should not be used as a substitute. Rhythm and symptoms will help direct the user to the appropriate Medicare "Group" and guideline.


DIAGNOSED RHYTHM
SYMPTOMS
COMMENTS
MEDICARE GUIDELINE NUMBER
A-V BLOCK
3rd DEGREE
ACQUIRED
W/SYMPTOMS
ASYMPTOMATIC
II-1
CONGENITAL
SEVERE BRADY
LESS SEVERE
II-2
2nd DEGREE
MOBITZ II
W/SYMPTOMS
ASYMPTOMATIC
II-5
MOBITZ I
SIGNIFICANT SYMPTOMS
ASYMPTOMATIC
III
FASICICULAR
W/SYNCOPE
II-3
ASYMPTOMATIC
III-6
CHB OR MOBITZ II DURING M.I.
PROPHYLACTIC
II-4
SINUS
BRADY
MUST DOCUMENT BRADY RELATED TO SYMPTOMS
MAJOR SYMPTOMS
BRADY <50 BPM
DIZZINESS OR CONFUSION
BRADY 50-59 BPM
DIZZINESS OR CONFUSION
FEW PATIENTS
BRADY
SIGNIFICANT SYMPTOMS
DUE TO MEDS
W/O SIGNIFICANT SYMPTOMS
III
S-A BLOCK SINUS ARREST
SIGNIFICANT SYMPTOMS
W/O SIGNIFICANT SYMPTOMS
III
TACHY
BRADY-TACHY
SIGNIFICANT SYMPTOMS
RECURRENT/ REFRACTORY VT
OVERDRIVE PACING
II
BRADY W/SVT
HIGH DEGREE AV BLOCK
BRADY ASSOC. W/SYMPTOMS
SINUS NODE DYSFUNCTION
MANY PVCs RUNS OF PVCs COUPLETS
LIFE THREAT
ATRIAL FIB PROLONGED R-R
W/O THIRD DEGREE A-V BLOCK
III
OTHER
CAROTID SINUS SYNDROME
SYNCOPE DUE TO BRADY
UNRESPONSIVE TO MEDS
VERY SUBSTANTIAL BRADY
LESS THAN 45 BPM
DUE TO LONG TERM DRUG THERAPY
II-6
BRADY
DURING SLEEP
III
UNDETERMINED CAUSE OF SYNCOPE
III

MEDICARE INDICATIONS

(Transmittal No. 968 3/16/83 Regulation Reference 42 CFR 405.310K)

GROUP I:

Conditions under which implantation of a cardiac pacemaker is generally considered acceptable or necessary, provided that the conditions are chronic or recurrent and not due to transient causes such as acute myocardial infarction, drug toxicity, or electrolyte imbalance. (In cases where there is a rhythm disturbance, if the rhythm disturbance is chronic or recurrent, a single episode of a symptom such as syncope or seizure is adequate to establish medical necessity.)

1. Acquired complete (also referred to as third degree) AV heart block with symptoms (e.g., syncope, seizures, congestive heart failure, dizziness, confusion or limited exercise tolerance).
2. Congenital complete heart block with severe bradycardia (in relation to age), or significant physiological deficits or significant symptoms due to the bradycardia.
3. Second degree AV heart block (also referred to as AV block and heart block) of Mobitz Type II with symptoms attributable to intermittent complete heartblock.
4. Second degree AV heart block of Mobitz Type I with significant symptoms due to hemodynamic instability associated with the heart block.
5. Sinus bradycardia associated with major symptoms (e.g., syncope, seizures, congestive heart failure); or substantial sinus bradycardia (heart rate less than 50) associated with dizziness or confusion. The correlation between symptoms and bradycardia must be documented, or the symptoms must be clearly attributable to the bradycardia rather than to some other cause.
6. In selected and few patients, sinus bradycardia of lesser severity (heart rate 50-59) with dizziness or confusion. The correlation between symptoms and bradycardia must be documented, or the symptoms must be clearly attributable to the bradycardia rather than to some other cause.
7. Sinus bradycardia which is the consequence of long-term necessary drug treatment for which there is no acceptable alternative, when accompanied by significant symptoms (e.g., syncope, seizures, congestive heart failure, dizziness or confusion). The correlation between symptoms and bradycardia must be documented, or the symptoms must be clearly attributable to the bradycardia rather than to some other cause.
8. Sinus node dysfunction with or without tachyarrhythmias or AV conduction block - i.e., the bradycardia-tachycardia syndrome, sino-atrial block, sinus arrest - when accompanied by significant symptoms (e.g., syncope, seizures, congestive heart failure, dizziness or confusion).
9. Sinus node dysfunction with or without symptoms when there are potentially life-threatening ventricular arrhythmias or tachycardia secondary to the bradycardia (e.g., numerous premature ventricular contractions, couplets, runs of premature ventricular contractions, or ventricular tachycardia).
10. Bradycardia associated with supraventricular tachycardia (e.g., atrial fibrillation, atrial flutter, or paroxysmal atrial tachycardia) with high degree AV block which is unresponsive to appropriate pharmacological management and when the bradycardia is associated with significant symptoms (e.g., syncope, seizures, congestive heart failure, dizziness or confusion).
11. The occasional patient with hypersensitive carotid sinus syndrome with syncope due to bradycardia and unresponsive to prophylactic medical measures.

GROUP II:

[redacted]

GROUP III:

Conditions which, although used by some physicians as bases for permanent pacemaker implantation, are considered unsupported by adequate evidence of benefit and, therefore, should not generally be considered appropriate uses for pacemakers in the absence of indications cited in the above two groups. Contractors should review claims for pacemakers with Group III indications with a view toward further claims development prior to denying the claim. The contractors should attempt, in further developing the claim, to determine whether the particular claim may actually meet the conditions of Groups I or II. In claims where this is not the case, or where such an event appears unlikely, the contractor may deny the claim.

1. **Syncope of undetermined cause.**
2. **Sinus bradycardia without significant symptoms.**
3. **Sino-atrial block or sinus arrest without significant symptoms.**
4. **Prolonged R-R intervals with atrial fibrillation (without third degree AV block) or with other causes of transient ventricular pauses.**
5. **Bradycardia during sleep.**
6. **Right bundle branch block with left axis deviation (and other forms of fascicular or bundle branch block) without syncope or other symptoms of intermittent AV block.**
7. **Asymptomatic second degree AV block of Mobitz Type I.**

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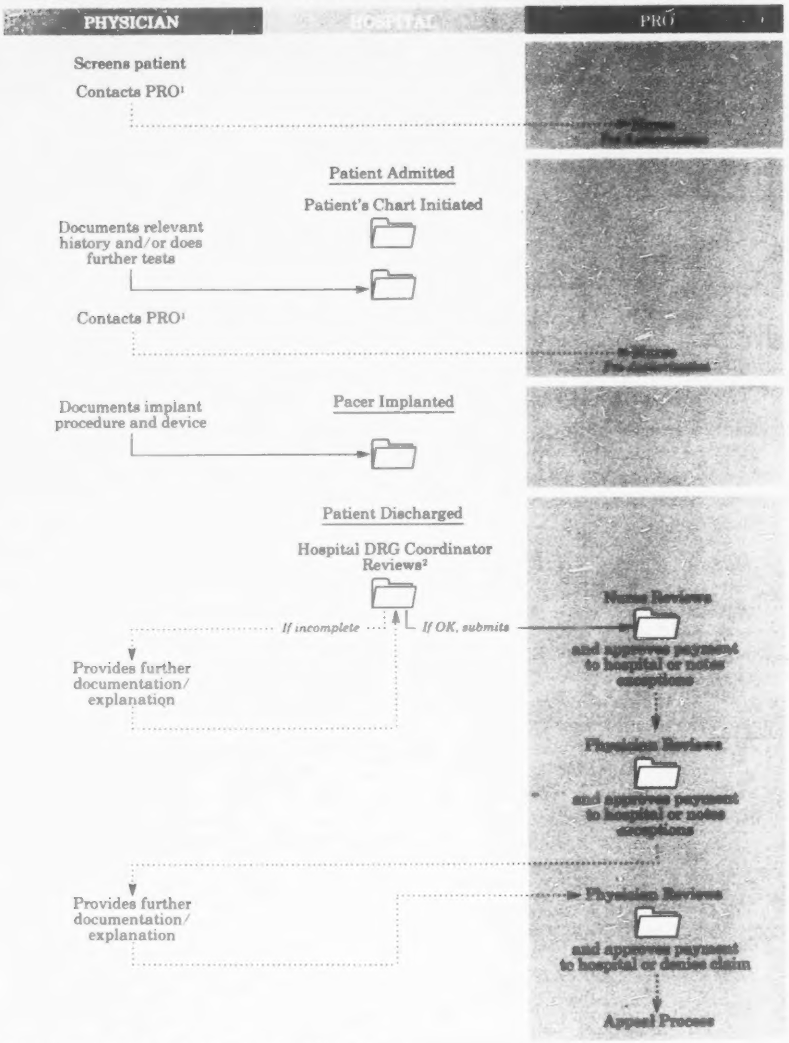
PACEMAKER IMPLANT

The Patient's Chart From Admission Through PRO Review


PHYSICIAN
HOSPITAL
PRO
Screens patient
Contacts PRO[1]
Patient Admitted
Patient's Chart Initiated
Documents relevant history and/or does further tests
Contacts PRO[1]
Documents implant procedure and device
Pacer Implanted
Patient Discharged
Hospital DRG Coordinator Reviews[2]
If incomplete
If OK, submits
Provides further documentation/ explanation
Nurse Reviews
and approves payment to hospital or notes exceptions
Physician Reviews
and approves payment to hospital or notes exceptions
Provides further documentation/ explanation
Physician Reviews
and approves payment to hospital or denies claim
Appeal Process

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[1] Required in some states, optional in others, and unavailable in others.

[2] Many institutions.

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HOWARD S. FRIEDMAN, M.D., F.A.C.P., F.A.C.C.
Chief, Section of Cardiology
Telephone: (718) 403-8265

May 15th, 1985

Senator John Heinz
United States Senate
Special Committee on Aging
Washington, DC 20510

Dear Senator Heinz:

I have reviewed the report by the Prospective Payment Assessment Commission (ProPac),HCFA's pacemaker guidelines and those of New York State Peer Review Organization. Despite a reduction in the length of stay for patients who have had pacemaker implantations in 1984 when compared to 1981, there has actually been an increase in the average cost per hospital discharge. This increase has been related to a substantial increase in the use of dual chamber devices (from 6% to 26%) and the attendant increase in operating room charges and what are termed electrophysiological studies. From what I can gather, ProPac has concluded that this is a justifiable increase that can be attributed to the advances in pacemaker technology and science .

Rarely, in my experience , has electrophysiological testing been helpful in deciding the need for pacemaker implantation. Only when pacemakers are being used as an anti-tachycardia device -- which is still investigational and not germane to the report -- would such testing be necessary. Specifically, for A-V conduction disturbances and/or sinoatrial dysfunction, electrophysiological testing is rarely useful in deciding which patient requires a permanent pacemaker. As you will note, in the HCFA guidelines clinical criteria are presented; there are no electrophysiological criteria.

Electrical testing that is used for deciding on dual chamber devices is also unreliable: Blood pressure responses during atrial pacing are compared to those during ventricular pacing. However, the relationship of such responses to clinical outcome has not been established. I have observed substantial blood pressure fluctuations in patients with single chamber ventricular demand pacemakers who are entirely asymptomatic.

The second question that the ProPac report raises is whether the increase in the use of dual chamber devices, from 6% to 26% of implants or even 95% of implants, as suggested by one pacemaker expert, is justified. I think not. Although they are some patients, those with the so-called pacemaker syndrome -- an uncommon complication following implantation of ventricular demand pacemakers -- and patients with marked left ventricular hypertrophy, who benefit from dual chamber devices, this group makes up a small percentage of patients who require pacemakers. Specifically, there is no evidence that dual chamber devices prolong life and the evidence that their widespread use would have a substantial impact on quality of life of many patients now receiving single chamber devices has not been demonstrated. The clinical trials that have been reported to support the more general use of dual chamber pacemakers is, in my opinion, scientifically "soft". There exists --, it seems to me -- a naive perception by ProPac that what is termed technologically more advanced should be routinely used and justifies medicare reimbursement.

Furthermore, the current reimbursement schedule for surgeons serves as an incentive for implanting dual chamber devices. In Brooklyn, surgeons are reimbursed by medicare $2,098.70 for "A-V sequential" devices, whereas the reimbursement for a single chamber device is $633.20. According to ProPac (page 18 of report) the average time required for implantation of single chamber devices is 49 minutes vs 79 minutes for dual chamber devices. It would seem therefore that the difference in reimbursement is not justified when considering the technical skills required of the surgeon or time that he spends in the operating room.

It would seem to me that medicare should reimburse for single chamber demand programmable devices that satisfy HCFA's guidelines for appropriateness of indication. The price of such devices is less than $2,000 as compared to more than $5,000 for the dual chamber units plus the additional charges of the surgeon. Also, pacemaker companies should be encouraged to produce multiprogrammable devices at a comparable price (it is time to stop paying for the research and development of these devices) and separate guidelines should be developed by

HCFA for the use of dual chamber devices.

As I reviewed the list of members of ProPac, I was unable to recognize any pacemaker authorities. I presume therefore that the report is based in part on the testimony of some reputed authorities. Recognized pacemaker experts are generally surgeons or cardiologists who implant these devices. Unfortunately, in my view, the relationship of some of these experts and the pacemaker industry has been too close. Although closer relationships of industry and academia has received more general acceptance, as it relates to pacemakers, this may not have always been desirable. Through honoraria for conferences and colloquia, support of pacemaker journals, and grants for clinical research, the industry directly or indirectly influences many of these experts. This is not meant to suggest criminality or even impropriety, but only that the relationships of the medical experts and the pacemaker industry should be examined for potential bias when assessing the testimony of some of the pacemaker experts.

HCFA Guidelines: 1) In general, electrocardiographic documentation should be part of the hospital record of patients who received permanent pacemakers; when not available, the reason should be noted in the chart. 2) Group I-(2) Severe bradycardia should be defined. 3) Second degree heart block of Mobitz type I should be relegated to group II. 4) Group I-(6) should be relegated to group II. 5) Group I-(7) "Long term necessary drug treatment for which there is no acceptable alternative" should be discussed in the patient's chart. In my own experience, there have always been acceptable alternatives. 6) Group I-(7) should be relegated to group II and "numerous premature ventricular contractions in association with sinus node dysfunction" should be reconsidered as an indication. 7) Group II-(2) Severe bradycardias should be defined. 8) Group II-(6) "The absence of acceptable alternatives" should be discussed in patient's chart. 9) Group II-(7) should only be viewed as an acceptable indication when electrophysiological testing has demonstrated pacemaker efficacy.

New York State Peer Review Organization pacemaker guidelines: "Conditions considered appropriate for pacemaker implantation" (5) and (6) do not by themselves serve as indications for pacemakers. In fact, I would recommend that HCFA's guidelines with modifications suggested be used by the Peer Review Organization for the State of

New York rather than this inaccurate abbreviated version.

Sincerely,

Howard S Friedman

HOWARD S. FRIEDMAN, M.D.
Associate Professor of Medicine
Downstate Medical Center, (SUNY)

HSF:df

CARDIO·PACE
MEDICAL

May 23, 1985

The Honorable John Heinz
Chairman
Special Committee on Aging
Washington, D.C. 20510

Dear Senator Heinz:

As you know, Cardio-Pace Medical has been trying to follow your lead.

However, in reading information about your recent Senate Select Committee on Aging hearings re: pacemaker fraud, waste and abuse as published in Technology Reimbursement Reports (copy enclosed), we are dismayed that HHS should consider establishing a separate Medicare DRG number for implantation of dual-chambered pacemakers as suggested by the GAO. We do not believe that a study based on data from twelve hospitals for out of approximately 5,000 hospitals in which pacemakers are implanted is statistically valid. Further, we believe that those hospitals may be institutions which previously operated under cost plus reimbursement programs between 1981 and 1984. We are also dismayed that the GAO saw fit to only deal with the four largest pacemaker manufacturers. We are beginning to wonder when and where small business fits into the picture. Obviously, it is in the best interest of the large manufacturers to have higher DRG reimbursement.

For your convenience, we are also enclosing reprints of two articles by Dr. Andrew Gage, a long time and well respected member of the pacemaker medical community. Two points made by Dr. Gage seem very clear:

1. In his opinion, approximately 10% of the patient population needs a sophisticated dual-chambered device.
2. For an industry that worked long and hard to develop longer lived pacemakers, it seems ridiculous to have dual-chambered pacemakers whose service lifetime is approximately one half that of the single-chambered models.

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St. Paul, Minnesota 55113 U.S.A.
Telephone: 612/483-6787
Telex: 297003 Cable: CPMED

We further disagree with the box on page 4 of Technology Reimbursement Reports. It shows a cost difference of $1,329 comparing single-chamber and dual-chamber devices. We believe that GAO overlooked:

a. the fact that dual-chambered devices last half as long. Therefore, if the average patient lives five years, there would be a necessity of each patient having to have, over his lifetime, two dual-chambered devices as opposed to one single-chambered device which may well be sufficient for the vast majority of patients over their lifetime.

b. They have also overlooked the fact that in the case of dual-chambered pacers, all of the associated costs of hospitalization, removal, and reimplantation of a new pacemaker were not included for the second implantation.

Further, Cardio-Pace Medical believes that the average single-chamber pacemaker currently sells for $4,100 to the hospital and the average dual-chamber pacemaker costs $5,500 -- a difference of $1,400 not $547. Secondly, the average lead is now selling for $500 or more and as dual-chamber devices utilize two leads as opposed to one in single-chamber devices, we have another difference of $500. Thus, the total difference between single-chamber and dual-chamber devices is $1,900 on the first implantation, plus an additional $5,500 on the second implantation for a total of $7,400, not counting the cost of the extra hospitalization. As testimony before your subcommittee indicated, there are 150,000 pacemakers implanted in the U.S. every year, and 25% of those are dual-chamber devices. Therefore, 37,500 units would be implanted at a $7,400 price differential, we are looking at $277,500,000 expended by Medicare, assuming that all the patients lived for a second implant. This is a worst case scenario. However, it is still a large number even if only 50% or 25% survived for a second implant.

Companies like Cardio-Pace Medical have been trying to work within the guidelines HCFA and the DRGs to provide high quality, efficacious products, at reasonable prices. Our pacemaker sells for $2,000 and under, depending on quantity and terms. Our VA contract price is $1,195.

Senator John Heinz
Page 3
May 23, 1985

The Company also believes that the quote from GAO regarding the manufacturers' decisions to provide product warranty in the U.S. market may also be in error. The enclosed copy of M-D-D-I Reports page 4, May 20, 1985 quotes the GAO with regard to warranties.

Senator Heinz, please let us state for the record that Cardio-Pace Medical is neither anti-DDD, anti-progress, or anti-anything. We did, however, take our cue from HCFA and the DRGs. We believe that high quality, efficacious, reliable products can be made and sold at far more reasonable prices than at present.

We at Cardio-Pace Medical have additional information. Our heart and soul cry for the opportunity to state our case as the big companies have stated theirs. We would be delighted to meet with you, members of your staff, or anyone else regarding the pacemaker situation. As we have written many letters to you and your colleagues in the past, we pray that our belief in the American system does not fall on deaf ears. We support your efforts!

Most sincerely yours,

CARDIO-PACE MEDICAL, INC.

Sid M. Barbanel

Sid M. Barbanel
President and CEO

SMB:srp

Enclosure

cc: Ronald Reagan, The President
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The Honorable Rudy Boschwitz
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cc: The Honorable Bruce Vento
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MEDICARE PACEMAKER REGISTRY WILL BE OPERATING BY JUNE 1986, FDA CHIEF YOUNG TELLS SENATE PANEL

FDA's registry of Medicare-reimbursed pacemakers will be in place by June 1986, FDA Commissioner Frank Young told a May 10 hearing of the Senate Select Committee on Aging.

Young said he anticipates that the process of formulating the registry regulations would begin "in less than six months." Following publication of the proposed rule, there will be a minimum of 180 days for comment, Young explained, pushing the targeted registry start-up date to approximately June 1986.

Committee chairman Heinz (R-Pa.) called the hearing to question the delay by FDA and the Health Care Financing Administration in implementing the registry.

The 1984 Deficit Reduction Act mandates that the registry be in place by Jan. 1, 1985.

Young asserted that the agency has "to have a registry that is machine real."

He said "it is important that we don't fire up a machine that is going to collect 200,000 reports per year...and not have tested it in some kind of pilot study to know what we are doing is right."

FDA has examined the Veterans Administration pacemaker registry, a national implant registry, and a device center contract registry as potential models for the FDA database, Young said.

"We found no registry that was already under way that we could adopt lock, stock and barrel," the FDA official stated.

In prepared testimony, Young also said that an FDA in-house task force report led the agency "to conclude that establishing and maintaining a registry in-house would pose substantial problems that might be resolved by contracting with a private organization."

He added that "an in-house registry would require additional computer equipment and storage capacity, as well as specialized computer staff that might be difficult to obtain."

A number of computer management firms, some specializing in cardiac pacemakers and leads, have contacted FDA about the registry, the agency chief said.

Hospital Payment Conditioned On Data Reporting

HCFA chief Carolyne Davis said her agency has been "developing a draft proposed regulation [to establish a registry] that is scheduled for publication later this year."

She said HCFA's plans "would require hospitals to report specified pacemaker information to intermediaries as a condition of Medicare payment."

The information would then be transmitted to FDA, which "would maintain the national registry, analyze the data submitted by manufacturers, and inform HCFA of cases where payment may be denied when devices are not returned when requested or test results are not reported."

In a summary of committee findings, Chairman Heinz said the Office of Management and Budget rejected HHS' request for $1.2 mil. and 11 personnel for FDA to implement and maintain the registry.

He said he hopes "to get a commitment from OMB" for the office "to be more fully cooperative with the needs of the FDA" with respect to funding a pacemaker registry.

DUAL CHAMBER PACEMAKERS ACCOUNTED FOR 23% OF PACER IMPLANTS IN 1984, UP FROM 5% IN 1981

Dual chamber pacemakers accounted for 23% of U.S. pacer implants in 1984 — up "dramatically" from 5% in 1981, the General Accounting Office estimates.

With both the increasing use and higher expense of dual chamber pacemakers, HHS should review the merits of establishing a separate Medicare diagnosis-related group for their implantation, GAO suggests.

It estimates that, during 1981, implantation of a dual chamber pacemaker cost over $1,300 more than use of a single chamber device *(see box)*.

GAO's report was released at a May 10 Senate Select Committee on Aging hearing on pacemaker issues. The hearing also focused on FDA's delay in establishing a registry of Medicare-reimbursed pacemakers *(see preceding story)*.

The study is based on data from 12 hospitals as well as the four largest pacer manufacturers — Cordis, Intermedics, Medtronic and Pacesetter Systems.

While the current Medicare DRG system may contain incentives for inappropriate underutilization of dual chamber models, a separate DRG could provide incentives for overuse of the dual chamber devices, the congressional accounting agency acknowledges.

Thus, GAO recommends that HHS expand its guidelines on the medical conditions for use of single versus dual chamber pacemakers.

COST DIFFERENCE BETWEEN SURGERIES INVOLVING SINGLE CHAMBER AND DUAL CHAMBER PACEMAKERS

	Single Chamber	*Dual Chamber*	*Difference*
Average pacemaker cost	$3,153	$3,700	$ 547
Average cost for leads	334	700	366
Average operating room minutes x cost	333	537	204
Average routine costs x average length of stay x average per diem rate	1,579	1,791	212
Total..............	$5,399	$6,728	$1,329

DUAL-CHAMBER PACEMAKERS ACCOUNTED FOR 23% OF ALL U.S. PACER IMPLANTS IN 1984, GENERAL ACCOUNTING OFFICE SAYS; HHS SHOULD CONSIDER SEPARATE DRG

Dual-chamber pacemakers accounted for 23% of all U.S. pacer implants in 1984, up "dramatically" from 5% in 1981, the U.S. General Accounting Office says in a report on Medicare cardiac pacemaker surgery payment policies.

GAO's study, released at a May 10 Senate special committee hearing on pacemaker issues, is based on data from 12 hospitals, as well as from the four U.S. largest pacer manufacturers: Cordis, Intermedics, Medtronic and Pacesetter Systems.

Because of the increasing use, and higher expense, of dual-chamber devices, HHS should consider setting up a separate diagnosis-related group category for the implants, GAO suggests.

The report, entitled "Medicare's Policies and Prospective Payment Rates for Cardiac Pacemaker Surgeries Need Review and Revision," estimates that during 1981, implantation of a dual-chamber device cost over $1,300 more than implantation of a single chamber pacer.

The report also points out that current rates for pacemaker DRGs overestimate the amount hospitals should pay for pacemakers. Specifically, the current "DRG payment rates for pacemaker surgeries do not reflect the economies hospitals can realize by obtaining discounts."

In its study of 1981 hospital procurement practices, GAO found that few of the surveyed hospitals were taking advantage of the "quantity discounts" available to them when purchasing pacemakers. "While data obtained from manufacturers and hospitals show discounts ranging from about 5% to over 60%, only three of the 12 hospitals reviewed obtained quantity discounts," GAO states. Seven other hospitals "could have obtained discounts based on the discount availability data we obtained," the report continues.

GAO found that only one of 11 hospitals in its survey coordinated physician pacemaker requirements so as to negotiate discounts, in part by asking for competitive bids from pacer manufacturers. "In fiscal year 1981 [that] hospital was able to obtain discounts of up to about 40% on an annual purchase of fewer than 50 pacemakers," the report notes.

GAO therefore recommends that when HCFA updates pacemaker DRG rates, it should "use data that are as current as possible to reflect the improved efficiency that should result from the incentives toward prudent pacemaker purchasing under Medicare's prospective payment system."

GAO also maintains that, since all four major pacemaker manufacturers now offer warranties for their products, Medicare's prospective pay rates for pacer replacements — which are based on 1981 data — "may be too high in view of the current availability of credits and the new incentives to seek them." Two major pacer manufacturers, who together account for about 34% of U.S. pacer sales, did not offer warranties in the U.S. until the first half of 1984, GAO notes.

"The manufacturers' recent decision to provide a product warranty in the U.S. market could have a material effect on hospitals' pacemaker costs because it appears that a substantial portion of the company's replaced units can be expected to be covered by warranties and thus subject to replacement at no cost," GAO states.

The failure of hospitals to return explanted pacers to manufacturers, however, makes it difficult for them and for Medicare to claim warranty credits, GAO states. Cost-saving warranty credits are also lost because of competitive marketing practices by pacer companies that offer payment incentives if their pacer is used to replace that of a competitor's explanted model, GAO notes.

American College of Cardiology

HEART HOUSE 9111 OLD GEORGETOWN ROAD BETHESDA, MARYLAND 20814 (301) 897-5400

June 24, 1985

The Honorable John Heinz
Chairman
U.S. Senate Special Committee
on Aging
SD-G33 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Senator Heinz:

The American College of Cardiology (ACC), a non-profit educational institution representing over 13,500 physicians specializing in the diagnosis and treatment of cardiovascular disease, followed with concern the hearing on cardiac pacemakers held by the U.S. Senate Special Committee on Aging on Friday, May 10, 1985. Documents available at the hearing, including your opening statement, the statement by Dr. Brendan Phibbs and press releases, have been reviewed by the Cardiac Pacemaker Committee of the College. The GAO report "Medicare's Policies and Prospective Payment Rates for Cardiac Pacemaker Surgeries Need Review and Revision" was also reviewed.

It is our opinion that the committee received one-sided information during its deliberations in May. The benefits of pacing enjoyed by literally hundreds of thousands of patients were virtually ignored in the testimony presented.

As your opening statement indicated, there, indeed, are currently over 400,000 older Americans living today with cardiac pacemakers. This is a testament to the rapid development of pacemakers as an effective, safe, reliable and acceptable technology used in the management of chronic disorders of cardiac rhythm.

It has been and remains the goal of the ACC to aid in establishing guidelines for sound medical practice and decision making where cardiac pacing is concerned. Therefore, on behalf of the ACC, I respectfully submit the following comments on issues raised during the hearing and request that this letter be added to the hearing record:

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JOHN ROSS, JR., M.D.

Immediate Past President
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Executive Vice President
WILLIAM D. NELLIGAN, CAE

1) The tenor of the May hearing neglected the genuine progress which has been made with regards to defining indications for pacemakers. In recent years, and particularly since the 1982 hearings of the Special Committee on Aging, significant advances have been made in reaching agreement by concerned parties--physicians, government officials, manufacturers, third party payors and others--on indications for pacemaker implantation. Specifically, the College joined with the American Heart Association in developing "Guidelines for Permanent Cardiac Pacemaker Implantation, May 1984," which were published in the August 1984 issues of Circulation and the Journal of the American College of Cardiology. A copy is enclosed for your information. The American Medical Association, North American Society for Pacing and Electrophysiology, American College of Physicians, Blue Cross/Blue Shield Association and others have also been involved in promulgating guidelines. This is a large and on-going volunteer effort by the private sector to assure quality patient care and efficient utilization of the finite dollars available to deliver such care.

2) The College was not asked to present its views before the committee in May. However, an individual member of the College did present testimony speaking for himself. It must be made clear that viewpoints expressed by members of the College do not necessarily represent the official position of the College. The College will be pleased to present its views on pacemaker issues if asked to do so.

3) We endorse the committee's interest in a registry of pacemaker devices both for purposes of tracking the performance characteristics of specific models and to obtain "natural history" reports of the patients who receive these systems. Such a registry should not be a "bean counting" exercise which simply logs pacer information at implant but should offer useful demographic data on regional differences in pacemaker usage, failure modes, and, perhaps, serve as a "Hotline" for physician notification. This type of registry is expensive and simply cannot be established by a government bureaucracy when funds have not been allocated.

4) We agree that the warranty statements of the individual manufacturers are confusing to the consumer and difficult to apply in a timely fashion which ensures appropriate reimbursement to those entitled to it. In fact, careful study may well show that, with the increased longevity of the majority of today's pacing systems, the dollar value of the warranty credit on the whole is rather small. It may well be that a policy conference on this topic which enlists the input of the pacemaker manufacturers, implanting physicians, hospital administrators, patients, and government fiscal intermediaries would iron out the problem and perhaps lead to a "generic" warranty.

In closing, we look forward to working in concert with you and your committee in the future to ensure rising standards of patient care. Specifically, we would hope to be asked to participate in any future hearings your committee may hold on pacemaker issues. We believe this will be an appropriate way to maintain a dialogue between parties concerned about proper application of pacemaker technology to medical care. If you would like more information about any of the above statements, please feel free to contact me at the College address.

Sincerely,

William W Parmley

William W. Parmley, M.D., F.A.C.C.
President

cc: John Ross, Jr., M.D., F.A.C.C.
J. Warren Harthorne, M.D., F.A.C.C.
Anthony N. DeMaria, M.D., F.A.C.C.
William D. Nelligan, CAE
William D. Coughlan, CAE

Appendix VI

federal register

FRIDAY, JULY 21, 1978
PART II

THE NATIONAL ARCHIVES OF THE UNITED STATES • 1934 •

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

■

MANUFACTURE, PACKING, STORAGE AND INSTALLATION OF MEDICAL DEVICES

Regulations Establishing Good Manufacturing Practices

[4110-03]

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

[Docket No. 75N-0140]

PART 809—IN VITRO DIAGNOSTIC PRODUCTS FOR HUMAN USE

PART 820—GOOD MANUFACTURING PRACTICE FOR MEDICAL DEVICES: GENERAL

Regulations Establishing Good Manufacturing Practices for the Manufacture, Packing, Storage, and Installation of Medical Devices

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document establishes a good manufacturing practice (GMP) regulation for the manufacture, packing, storage, and installation of medical devices. This regulation implements a provision of the Medical Device Amendments of 1976.

EFFECTIVE DATE: December 18, 1978.

FOR FURTHER INFORMATION CONTACT:

Edward J. McDonnell, Bureau of Medical Devices (HFK-130), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Avenue, Silver Spring, Md. 20910, 301-427-8120.

SUPPLEMENTARY INFORMATION: On May 28, 1976, the Medical Device Amendments of 1976 (Pub. L. 94-295) were enacted into law, amending the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 201 et seq.). Section 520(f) of the act (21 U.S.C. 360j(f)) provides the agency with authority to prescribe a regulation requiring that the methods used in, and the facilities and controls used for, the manufacture, packing, storage, and installation of medical devices conform to current GMP requirements, as prescribed in the regulation, to assure that devices are safe and effective and otherwise in compliance with the act.

The proposed device GMP regulation was published in the FEDERAL REGISTER of March 1, 1977 (42 FR 11997). Other FEDERAL REGISTER notices concerning this regulation are cited below in the section of this preamble on "History of Device GMP Regulation."

The Commissioner recognizes that the medical device industry consists of manufacturers whose devices and manufacturing processes differ significantly. This diversity of manufacturing processes affects the development of comprehensive GMP regulations that will apply to all finished device manufacturers. The Commissioner believes that an "umbrella" GMP regulation applicable to all finished device manufacturers should not be so specific as to prescribe for each manufacturer the precise details of what it must do and how it must undertake to manufacture devices. Rather, the GMP regulation should contain general requirements in specific areas of concern applicable to all manufacturers, specify additional requirements for certain devices, and require each manufacturer to supply the details which are appropriate for its device by developing for the manufacture of each device a detailed set of procedures which implement the GMP regulation. FDA will examine such procedures to determine whether a manufacturer is complying with the regulation.

The Food and Drug Administration (FDA) expects to publish additional GMP regulations applicable to specific types of devices. These future regulations will supplement the "umbrella" GMP regulation and will be of two types: One will contain requirements that will apply only to generic types of devices or classes of devices, e.g., pacemakers; eyeglasses, etc., the other will contain requirements that will apply to certain devices or cross-class characteristics or processes, e.g., sterile devices, plastics, electrical properties, etc.

The "umbrella" GMP regulation imposes additional requirements on "critical devices," defined as devices that are intended for surgical implant into the body or devices intended to support or sustain life and whose failure to perform when properly used can be reasonably expected to result in significant injury to the user. Other devices are called "noncritical" devices and are subject to provisions of the regulation that are not limited to critical devices. The distinction is based on the additional risks to users that are posed by defective critical devices.

This distinction was incorporated into the proposed regulation published in the FEDERAL REGISTER of March 1, 1977 (42 FR 11997), by means of a two-tier approach that denotes general requirements applicable to all devices (critical and noncritical) and specific requirements applicable only to those devices classified as "critical."

IMPORTANCE OF DEVICE GOOD MANUFACTURING PRACTICE REGULATION

Today, increasing numbers of Americans are experiencing the benefits of modern medical technology in the treatment of injury and disease. Device manufacturers, adapting advances in space and medical technology, are producing a broad spectrum of varied and complex life-sustaining, life-supporting devices. In addition, a growing number of other, less sophisticated devices also have been made available to health professionals for improved health care services delivery. At the same time, Americans are also more likely to come in contact with devices. Data compiled by the American Hospital Association show that, during 1976, there were more hospital admissions, outpatient visits, and physician visits in the United States than in any preceding year (Ref. 1). As a consequence, more devices than ever before were used by and on Americans in the diagnosis and treatment of medical conditions.

Consumers who use devices differ from other consumers in an important respect. They are usually injured or diseased, and thus are a population at risk. These patients, and the many health professionals who diagnose and treat their conditions, depend on and trust device manufacturers to produce safe and effective devices of high quality. Although the degree of a patient's dependence on a device varies according to the nature of the illness, it is clear that the application of defective devices to patients already at risk because of illness could have a deleterious or even catastrophic effect on their recovery.

Based on FDA's experience, the Commissioner believes that it is vitally important that devices be manufactured in accordance with quality assurance principles that help prevent the production of defective products that can endanger consumers. In monitoring device recalls, FDA has found that, too often, device manufacturers have fallen short in meeting the expectations of those who need and depend upon high quality medical products. During the past several years, FDA monitored approximately 1,000 device recalls. Many of these resulted from manufacturers' failure to follow good manufacturing practices. For example, of 232 device recalls monitored by the FDA from October 1976 through November 1977, FDA believes that 198 of them were attributable to poor manufacturing practices.

The quality assurance program mandated by this regulation is designed to be preventive. The device GMP regulation requires all device manufacturers to design, implement, and continually monitor a comprehensive quality assurance program. This quality assurance program may be appropriately tailored to satisfy a device's special manufacturing requirements, but it may not compromise strict quality sonnel because it is common practice in a small company for the same individual to perform both a quality assurance and a production function. Other comments said FDA should not concern itself with the organizational structure of a company because the structure has nothing to do with good manufacturing practices.

The Commissioner is revising the requirement that a manufacturer have in its organization a quality assurance unit that is organizationally independent of, or separate from, units performing manufacturing operations. The regulation now requires that each manufacturer prepare and implement quality assurance procedures to assure that a formally established and documented quality assurance program is performed. After reflecting on the concerns raised by small manufacturers on the implications of organizational requirements, the Commissioner has determined that it would be unwise at this time to mandate that each manufacturer have a separate quality assurance unit. In making this change, the Commissioner recognizes that effective quality assurance procedures depend more on the commitment of top management to exercise leadership in planning, designing, implementing, and assessing the quality assurance program than on the establishment of a separate quality assurance unit. Although many manufacturers have determined that an objective and accountable quality assurance process can be achieved most effectively by establishing an independent quality assurance unit, the Commissioner believes the desirable objectivity and accountability can be achieved without dictating organizational requirements. FDA is more interested in the adequacy and appropriateness of the quality assurance program that each manufacturer has developed than in the organizational structure of the company.

Because the regulation no longer requires each manufacturer to have in its organization a quality control unit, the Commissioner finds it unnecessary to define the term "quality control unit," and he has deleted the definition from the final rule.

The Commissioner has also amended the regulation to provide that, where possible, a designated individual(s) not having direct responsibility for the performance of a manufacturing operation shall be responsible for the quality assurance program. Although production and quality assurance personnel share a common goal of assuring that high quality devices are produced, their interests may sometimes conflict in the short run as decisions are made that will affect a company's output. The Commissioner has used the words "where possible" in this requirement because he recognizes that for very small companies (one or two employees) it would be impossible for the designated quality assurance individual not to have responsibility for a production function.

31. Several comments said individual employees should be able to check and verify their own work. They argued that if such checks are not done by the employees themselves, a production foreman or supervisor should perform them, because these individuals are more familiar with the manufacturing operations than is an independent quality control person.

The Commissioner never intended that production personnel should not be able to check or inspect their own work. Checking and inspection activities are highly desirable and help to assure that devices are fit for their intended use. But adherence to an adequate quality assurance program provides a further check to assure that material and production specifications are met. In an effective quality assurance program, the checking and inspection for adherence to specifications that are done by production and quality assurance personnel alike complement one another and provide greater assurance that high quality devices are produced.

32. Several comments on proposed § 820.20 suggested that the term "quality control" be changed to "quality assurance" since the latter term is more inclusive and familiar in industry.

The Commissioner agrees with the suggestion, and § 820.20 is changed accordingly. The Commissioner has changed the term "quality control" to "quality assurance" wherever the term appears in the final regulation.

33. Several comments on the proposed responsibilities of the quality control unit under § 820.20(a) said manufacturers should be responsible only for those devices they manufacture and not for those manufactured for them by other firms under contract.

The Commissioner disagrees with the comments and believes a manufacturer should have adequate control measures designed and in force to assure that any firm manufacturing a device for it under contract complies with the GMP regulation.

34. Several comments said the quality control unit need not check in-process production of noncritical devices because it has the authority to reject the finished device if that should prove necessary.

The Commissioner disagrees with these comments because he has not mandated any in-process checks during the production of noncritical devices. It is the manufacturer's responsibility under § 820.5 to determine whether such checks are necessary for the production of noncritical devices. Through inspections, FDA will review these management decisions and quality assurance procedures and communicate to the firm its observations on the adequacy of, and the adherence to, a manufacturer's procedure for in-process checks.

35. Several comments said the quality control personnel have no need to review production records, as these records have no bearing on the quality of the device.

The Commissioner disagrees. An effective quality assurance program requires a careful and periodic review of all elements of manufacturing practice that have a bearing on the quality, safety, and effectiveness of a device. A careful review includes the verification and evaluation of each quality factor that affects production to assure that all processing and performance specifications are met. A review of production and other records by quality assurance personnel is fundamental to the implementation and maintenance of an effective quality assurance program. The review of production records provides management with feedback on the results of the production activity and with assurance that production, process, and performance specifications are being met.

36. Several comments urged that the requirements of the quality control function, as stated in proposed § 820.20(a), be clarified.

The Commissioner agrees, and § 820.20(a) is revised to clarify the requirements of the quality assurance program.

37. Many comments expressed reservations about proposed § 820.20(b), which requires audits of a manufacturer's quality assurance program. These comments objected to any provision that would require the disclosure of internal audit reports to FDA. It was stated that any requirement which would result in disclosure of internal audit reports would lead to a weakening of the audit system because firms would be reluctant to be candid when expressing in writing the results of their internal audits if this information were freely available to FDA and to the public under the Freedom of Information Act. It was further argued that concern about self-incrimination would result in the preparation of "sanitized" audit reports. A few comments suggested that, if procedures for internal audits are required, firms should have the flexibility to provide FDA with complete summaries of the outcome of an audit and any decision resulting from observations uncovered during the audit. It was further stated that a summary should be sufficient to enable FDA to determine whether audits have been performed and to

verify that appropriate action was taken by management.

The Commissioner believes that planned and periodic audits of quality assurance should be undertaken because the maintenance of a useful quality assurance program requires that the program be subjected to periodic review. In addition, the proper implementation of an audit system for quality assurance can result in cost-savings to the manufacturer if problem areas are identified and corrected.

The Commissioner shares the concerns of the comments and the Device GMP Advisory Committee that general FDA access to audit reports would tend to weaken the audit system. He believes that auditing of quality assurance programs is important, and he recognizes the need to maintain a degree of confidentiality if audits are to be complete and candid. Therefore, the Commissioner has decided that FDA must require each manufacturer to conduct periodic audits of its quality assurance program and to prepare audit reports. The Commissioner has also concluded that FDA must routinely inspect and copy manufacturers' internal audit procedures. However, as a matter of administrative policy, FDA will not request inspections and copying of the reports of audits of a manufacturer's quality assurance program when FDA conducts routine surveillance of a manufacturer's compliance with device GMP's. When FDA needs to determine whether a manufacturer is conducting audits in accordance with the regulation, a designated FDA employee may request a responsible official of the manufacturer to certify in writing that the manufacturer has complied with § 820.20(b). Upon receiving such a request, the official is required to submit, or to have another responsible official of the manufacturer submit, the certification of compliance. A person who submits a false certification is liable to prosecution under 18 U.S.C. 1001 and 21 U.S.C. 331(q)(2).

The one exception to FDA's policy of not seeking access to reports of audits of quality assurance programs is that FDA may seek production of these reports in litigation under applicable procedural rules, as for other otherwise confidential documents.

It should be stressed that FDA's policy of not generally seeking access to audit reports applies only to reports of periodic audits (as defined in § 820.3(b)) of a manufacturer's quality assurance program, not to any records concerning particular devices or any other records concerning quality assurance or production. Records required under other sections of part 820, e.g., §§ 820.161 on finished device inspection, 820.162 on failure investigation, and 820.198 on complaint files, are subject to routine FDA inspection and are not governed by the policy in § 820.20(b) concerning FDA access to audit reports.

38. Many comments on proposed § 820.25 *Personnel* said the requirement that personnel have adequate educational background, training, and experience was too restrictive and that the phrase "qualifications and experience" was sufficient.

The Commissioner disagrees with these comments because the stated requirements are not too restrictive. The requirement of "sufficient personnel with the necessary education, background, training, and experience to assure that all manufacturing operations are correctly performed" is a flexible one. In the Commissioner's opinion the suggested term "qualifications" would include education, background, and training.

39. Many comments said training programs in proposed § 820.25(a) need not be documented and such documentation would create unnecessary paperwork and expense without achieving any significant benefit.

The Commissioner disagrees with the comments, but § 820.25(a) is revised in the final regulation to require that all personnel have the necessary training to perform their assigned responsibilities, but only to require documented training programs where such programs are necessary to assure that personnel have a thorough understanding of their jobs. He believes it is essential that the manufacturer formally recognize any training required for the performance of specific work by its employees. Where no training programs are necessary, the manufacturer is not required to implement an unnecessary program.

40. Many comments objected to the requirement in proposed § 820.25(a) that a documented training program be in effect for quality control personnel regarding defects and errors likely to be encountered in their individual control functions.

The Commissioner agrees with these comments, and § 820.25(a) is revised in the final regulation to eliminate the need for a documented training program on defects and errors for quality assurance personnel. However, he is revising and expanding this section to require manufacturers to strive for "defect awareness" by all employees. The final regulation requires that all employees be made aware of device defects that may occur from the improper performance of their specific jobs. Quality assurance personnel shall be made aware of defects and errors likely to be encountered as part of their individual quality assurance function.

41. Many comments said on-the-job training was more effective than a documented training program and best served to provide the necessary experience required by the regulation.

The Commissioner recognizes the value and desirability of on-the-job training programs and advises that § 820.25(a) in the final regulation allows for such training.

42. Several comments concerning the personnel health and cleanliness requirements in proposed § 820.25(b) said this provision should apply to sterile device manufacturers only.

The Commissioner disagrees with the comments because devices other than sterile devices, e.g., diagnostic products, may be adversely affected by poor personnel health and cleanliness practices. However, he points out that the requirement applies only to the extent that the cleanliness, health, and attire of personnel in contact with the device or its environment may affect the device.

43. Several comments said proposed § 820.25(b), concerning personnel health and cleanliness, was under the purview of the Occupational Safety and Health Administration, not FDA.

The Commissioner disagrees with the comment and has determined that the Occupational Safety and Health Act (OSHA) regulations do not include all of the personnel health and cleanliness requirements needed in this regulation, which aims at protecting device users from defective devices rather than protecting manufacturing employees from job-related hazards. Although there are some areas of common interest, the Commissioner believes that this regulation does not conflict with OSHA regulations.

Buildings

44. Many comments objected to the use of the word "prevent" in proposed § 820.40 *Buildings* in the provision that facilities provide adequate space to prevent mixups and in other parts of the proposal. The comments agreed that "prevent" is an absolute and connotes an unattainable goal. The comments suggested that the term "prevent" be changed to "designed to prevent."

The Commissioner agrees with the suggestion, and the final regulation is changed accordingly.

45. Several comments objected to the requirement in proposed § 820.40 that buildings in which manufacturing, assembling, packaging, packing, holding, testing, and labeling operations are conducted shall be of suitable design and contain sufficient space to facilitate adequate cleaning, maintenance, and other necessary operations. It was argued that these requirements should apply only when the device itself may be affected if a building were improperly designed or

corals.

COMPANY CONFIDENTIAL

Report

Date: September 15, 1980

To: Distribution

From: S. Solomon/ A. DeHaan SS for AD

Subject: TRIP REPORT ON VISIT TO SANDIA LABORATORIES, ALBUQUERQUE, N. MEXICO

On September 4 and 5, 1980, A. DeHaan and S. Solomon visited Dr. Samuel Levy, Lithium Battery Development, at Sandia Laboratories and Dr. Charles Leedecke, Ceramics Development Division. Sandia Laboratories is a Department of Energy facility administered by Western Electric Co. and located on Kirtland Air Force Base, Albuquerque, New Mexico. The facility employs approximately 7000 highly professional employees and is engaged in basic research and development in all areas of energy technology.

Dr. Levy has been with Sandia for 19 years and has several publications concerning lithium battery technology. Dr. Leedecke joined Sandia 2 years ago and has provided support to the battery group by supplying glass prototypes for feedthrus. He is also engaged in promoting production of improved glasses developed at Sandia, with feedthru manufacturers.

Mechanism of Corrosion

Dr. Levy was familiar with our observations on feedthrus degradation from previous conversations with Messrs. DeHaan and Solomon. We had stated that the cells in question were now under qualification tests for future use. He presented a model for the degradation using a Li/SO_2 cell with a LiBr-acetonitrile electrolyte. The essential features of the model involve:

1) Underpotential deposition of lithium on the glass at the negative electrode. The ability to deposit lithium below the Nernst value of -3.2V is based on the ability of components of the glass to complex with Li^+ which are absorbed on the glass surface. This feature of the glass to donnte electron to the Li^+ lowers the potential required to plate out lithium as the metal.

2) Reaction of plated lithium with metal oxides in the glass produces free silicon and alkali silicates.

$$4Li + SiO_2 \longrightarrow 2Li_2O + Si$$

$$Li_2O + SiO_2 \longrightarrow Li_2SiO_3$$

$$2Li_2O + SiO_2 \longrightarrow Li_4SiO_4$$

These compounds not only represent soluble degradation products of the glass but provide electrical conductivity paths within the glass to continue deposition of Li.

3) Censing of the reaction occurs when a complete monolayer of Li metal has been built up across the feedthru. When this happens deposition of Li^+ on Li metal can only occur at full Nernst potential.

Analytical Methods

The evaluation of corrosion was determined by either:

1) Measurement of the average thickness of uncorroded glass in the header.

2) Measurement of the capacity of the cell after storage under varying load, time, and temperature conditions.

3) Lithium was identified in the degradation product matrix by Secondary Ion Mass Spectrometry (SIMS), its ability to generate H_2 when reacted with water, and by measurement of the Li/S ratio.

Glass Composition

Based on the model described above Dr. Leedecke undertook the formulations of new glass compositions which would likely show resistance to feedthru degradation. Commercial glass showed a degradation rate of 0.04 mm/yr. A Corning glass designated 1723 improved it one order of magnitude to 0.004 mm/yr, while a Sandia formulation, TA 23, lowered the corrosion rate to<0.001 mm/yr.

Dr. Leedecke stated that Fusite also has a glass designated 108 that was a factor of 2 better than the commercial grades.

It was learned however that several problems exist in the availability and compatibility of many of the glasses. Dr. Leedecke has approached Fusite for the manufacture of their TA 23 glass, however Sandia is not presently in a position to provide them the technology until their patent position is established. A rough estimate for this time is six months, to which must be added an additional six months for development of production capabilities.

Additionally the TA 23 glass is designated to be used with metal having expansion coefficients of $100\mathrm{X}1\bar{0}^{7}/^{\circ}\mathrm{C}$. This would include metals such as molybdenum and Kovar. Thus in the Cordis feedthru if the center pin were converted to molybdenum the Sandia glass would be compatible. However molybdenum does not lend itself to welding and new methods of attaching the anode assembly would have to be explored. Kovar was not recommended because of its high expense and its dependence on importation from South Africa.

[illegible]

The Corning 1723 glass is now being used by Mallory. Dr. Leedecke mentioned that they had experienced sealing problems under 1200°C however he stated that he was able to effect successful seals at 1050°C. The 1723 likewise does not lend itself to bonding with stainless steel and would require change in the metallics of the feedthru for Cordis. Mallory has doctored the glass with alumina to allow it to be used with tantalum.

Evaluation of Cordis Feedthru Based on Corrosion Model

Dr. Levy was shown SEM photographs of Cordis Feedthrus which had undergone degradation over approximately 6 months and 1 year time periods. We asked him to give his best evaluation as to the life expectancy of these samples. Although somewhat reluctant to make a prediction because of the differences in the system between his studies and Cordis, he did make the following points:

1) Feedthru degradation is temperature dependent. All of the corrosion rate studies he had carried out previously were at elevated temperatures, i.e. 70 - 80°C.

The fact that our cells are operated at body temperatures for the major amount of time should diminish the corrosion rate well below that which he observed.

2) The rate of corrosion is linear. Although it is difficult to quantitate the degree of corrosion, it is qualitatively obvious that Cordis feedthrus have retained their properties to a much greater extent in one year than had those studied at Sandia in 3 months. Using comparable measurement techniques Cordis feedthru degradation would be more likely on the order of 1% per year. If one extrapolates to a five year period, expected corrosion would approximate 5%. It should be made clear that this estimate applies only to vertical corrosion of the glass matrix and not to the extent of conductive bridging.

3) Certain features of present Cordis glass composition prohibit degradative attack. Calculation of free energies of reaction of various oxides found in glass composition demonstrate that BaO is one of the less reactive compounds toward lithium. Other than SiO_2, barium oxide is the most abundant compound in our present Fusite compostion.

4) Use of barriers to mask the glass from contact with electrolyte is at best a stopgap measure. Materials used for this previously have been PTFE and Halar ®, a chlorinated fluorocarbon.

Choice of material should be predicated on low permeability toward Li^+ and good bonding characteristics toward both glass and metal. Dr. Levy was not familiar with the merits of polypropylene in this regard.

5) Of the two aspects of the corrosion reaction 1) vertical degradation leading to potential stresses and mechanical failure of the feedthru, and 2) formation of conductive bridges between terminals, it appears that the latter is of more concern in the Cordis cell system. Evaluation of this is essential for prediction of future integrity of all feedthrus.

Dr. Levy will deliver a paper during the week of October 6 - 10 to a meeting of the Electrochemical Society in Hollywood, Fla. He has stated that he would welcome a visit to Cordis and would try to arrange time for further discussions with Cordis personnel.

DISTRIBUTION

D. Bump
D. Hart
H. Hershenson
O. Jimenez
W. Oates
J. Pagones
S. Saulson
G. Smith
H. Tataria
E. Withers

[illegible]
Miami, Florida 33152, USA

Telephone 305-551-2000
Telex 6811112

Tom — As requested — your copy. JAC

Exhibit 3-6

December 9, 1982

CORDIS CONFIDENTIAL

Food and Drug Administration
Bureau of Medical Devices
8757 Georgia Avenue
Silver Spring, MD 20910

ATTN: Mr. Donald Dahms

Dear Mr. Dahms:

With reference to our discussion last week and your questions this week about the achieved reliability of Cordis 190A and 190E pacemakers, we believe it would be very useful for you to read our Product Updates that were published and distributed to the field in April and October, 1982, as part of our continuing program to keep our physicians informed about the reliability of Cordis pacemakers. As mentioned to you, information copies were sent at the same time to the local FDA office and to Mr. Rahmoeller in line with our usual practice on such matters. Since we believe the information in the Updates should answer your questions, we are sending you copies via Mr. Richard Morey.

You will note that both Lambda 190A and 190E continue to demonstrate overall reliabilities that meet or exceed the values predicted and described in the original labeling these models (attached). The achieved reliabilities (cumulative survival) at 77 and 61 months for 190A and 190E are 0.947 and 0.958, respectively. The average malfunction rate (percent/implant month) has also been relatively stable over the considerable time of implant.

Our reliability predictions assumed that most of the malfunctions would involve the electronic circuit and might occur suddenly without warning. In fact, more than half of all malfunctions were caused by comparatively benign early battery depletions. As stated in the October Update, the three major categories of verified malfunctions involve batteries (53% of all malfunctions), circuit boards (28% of all malfunctions) and reed switches (6% of all malfunctions). These three categories, therefore, represent 87% of all verified malfunctions, the remaining 13% being due to miscellaneous causes.

Approximately 31,000 190A and 190E pacemakers have been implanted world-wide. As stated in the Update, malfunctions due to batteries, circuit boards, and reed switches represent 2%, 1.1%, and 0.2% of the total registered implants. Therefore, in answer to your question regarding the number of malfunctions, the following table summarizes our experience.

TABLE 1

	1982	Total Nov., 1975 to Present (85 months)
Battery Depletion	112	579
PW Board	186	349
Reed Switch	9	67
Miscellaneous	28	148
TOTAL	335	1,143

In response to your other question about the time for wiring board malfunctions, it ranges from about 2 to 5 years with an average of 45 months.

While we of course wish the number of malfunctions were lower, the fact remains that the overall achieved reliability of the Lambda 190A and 190E pacers over this long period of time has met our labeling predictions.

We trust that you will find this material useful in answering your questions. We shall of course be happy to discuss any further questions you may have after reading this material.

Sincerely,

Joseph J. Schwoebel

Joseph J. Schwoebel
Manager, Regulatory Affairs

JJS/vm
Enclosure

FDA 12/7/83 [illegible]

109-2

CONFIDENTIAL

Date: August 19, 1983

To: Distribution Site/Location:

From: J. Pagones

Subject: Gamma Cells and Gamma Pacers - Task Force

As you know, we see a steadily increasing number of early battery depletions (EBD) in Multicor Gamma Pacers, primarily Model 334. We have set up Task Force to (1) define the extent of the problem based upon existing data and traceability records (2) determine if possible the underlying cause(s) of the depletion. The Task Force consists of Oscar Jimenez, Don Hart, Dr. Bump, Ron Gjertson, Harshad Tataria, and Phil Watson. Oscar will serve as the Task Force Leader. The Task Force will utilize the services of other people on a priority basis, for example, Dave Colbert, Regulatory Affairs, etc., but reporting and evaluation must be accomplished through the Task Force in order to avoid tangential efforts and duplicative reporting. The Task Force should meet immediately to define sub-tasks and meet frequently thereafter during the next 6 weeks, which is the estimated life of the Task Force.

At present, there are approximately 100 EDB's confirmed and unconfirmed, mostly from Model 334.

The definition and isolation of the problem must proceed rapidly (within the next 3 weeks) in the event it is appropriate to publish information in the forthcoming October Product Update.

I shall expect at least weekly summation of results for my further dissemination to upper management.

JP:vm

cc: Task Force:
- D. Bump
- R. Gjertson
- D. Hart
- O. Jimenez
- H. Tataria
- P. Watson

Information copies: D. Colbert, F. Fischer, H. Hershunson, K. Jonus, B. Nickerson, S. Saulson, R. Spencer, R. Smolowitz, N. Weldon, J. Schwoebel

Memorandum

cordis

109-1

CONFIDENTIAL

Date: August 19, 1983

To: Distribution

Site/Location:

From: J. Pagones JP

Subject: Gamma Cells and Gamma Pacers - Task Force

As you know, we see a steadily increasing number of early battery depletions (EBD) in Multicor Gamma Pacers, primarily Model 334. We have set up Task Force to (1) define the extent of the problem based upon existing data and traceability records (2) determine if possible the underlying cause(s) of the depletion. The Task Force consists of Oscar Jimenez, Don Hart, Dr. Bump, Ron Gjertson Harshad Tataria, and Phil Watson. Oscar will serve as the Task Force Leader. The Task Force will utilize the services of other people on a priority basis, for example, Dave Colbert, Regulatory Affairs, etc., but reporting and evaluation must be accomplished through the Task Force in order to avoid tangential efforts and duplicative reporting. The Task Force should meet immediately to define sub-tasks and meet frequently thereafter during the next 6 weeks, which is the estimated life of the Task Force.

At present, there are approximately 100 EBD's confirmed and unconfirmed, mostly from Model 334. The following pertains:

1) The average implant time to depletion is approximately 30 months, the range 0 to 35 months.

2) Tear-down analysis on a number of the field returns indicates the so-called Type II depletion mechanism, i.e., copper plating through the separator and forming a couple. Concurrently, there is also evidence of feedthrough corrosion and interaction.

3) Plots of field returns indicate both a random and systematic depletion mechanism from a statistical viewpoint.

4) Many of the EBD's can be traced to cells to made during the summer of 1980 prior to protection (polyethylene, then [redacted]) of the feedthrough (October 1980), and also prior to x-ray of cells and pacers (October 1981) and improved separator inspection (January 1982). There are significantly fewer discrepancies after October 1980.

5) In-vitro test results, as well as reserve sample test results, parallel field experience, i.e., reserve samples during the period of summer 1980 have depleted prematurely during the course of long-term testing under the 115K ohm load.

6) High temperature studies suggest a first order failure mode associated with a non-protected feedthrough insulator that can be extrapolated to a 30-36 month period at 37°C.

7) A number of feedthroughs used during the summer 1980 period were subject of MRR's.

8) The end-of-life on field returns includes both precipitous rate decrease and loss of output as well as slow rate decrease and diminished loss of output.

The foregoing facts are tentative and based upon present information and statements. A primary function of the Task Force is to confirm the above as well as to develop new facts.

The definition and isolation of the problem must proceed rapidly (within the next 3 weeks) in the event it is appropriate to publish information in the forthcoming October Product Update.

I shall expect at least weekly summation of results for my further dissemination to upper management.

JP/vm
cc: Task Force: D. Bump
R. Gjertson
D. Hart
O. Jimenez
H. Tataria
P. Watson

Information copies: D. Colbert, F. Fischer, H. Hershenson, K. Jones, B. Nickerson, S. Saulson, R. Spencer, R. Smolowitz, N. Weldon, J. Schwoebel

Date: September 22, 1983

To: Distribution Site/Location:

From: J. Schwoebel

Subject: Special Audit - Gamma Battery Cell Depletions

There have been 134 premature Gamma Battery depletions (less than 5 to 7 years of service life) confirmed to date. Approximately 65% of these failures are from lots manufactured over a nine week period in mid-1980.

At my request, Frank Gregorio audited Gamma Cell production records to determine if there is a correlation between failures in the high risk group and production factors. While no singular factor is apparent, there are many process anomalies in the suspect timeframe to indicate an overall lack of control. It is suggested that our power source technical personnel now evaluate the findings to possibly identify the root cause of our failures.

I believe Frank has done an excellent review of our data, having spent 150 manhours on the task. His effort represents the only thorough review ever performed of the 6000 pages of Gamma cell production history records. The facts presented in the report will undoubtedly help Cordis to analyze Gamma battery failures and plan appropriate actions.

JJS:mda

Distribution:
D. Bump
F. Fischer
R. Gjertson
D. Hart
H. Hershenson
O. Jimenez
J. Pagones
S. Saulson
H. Tataria
P. Watson

Date: September 21, 1983

To: J. Schwoebel Site/Location:

From: F. Gregorio FG

Subject SPECIAL AUDIT - GAMMA BATTERY CELL DEPLETIONS

INTRODUCTION

The following report details the findings of a special audit conducted during September, 1983 by Regulatory Affairs. The audit consisted of an extensive, comprehensive review of the environment surrounding the manufacture, testing and release of gamma battery cells by Bldg M Power Source Engineering (PSE) during 1980.

A search was made to identify any correlation which exists between lots of gamma batteries experiencing significant Early Battery Depletions in the field and lots not suffering premature depletion Attachment 1 is a list of the lots having the most failures (terme "high risk").

The search encompassed review of over 6,000 pages of documents, in the following areas:

A) Component Lot usage records for Gamma lots 1080 to 3680 inclusive Location - Plant 7G.

B) Batch production records - gamma lots 1080 to 3680 inclusive Location - 7G.

C) Gamma Battery shipment records for 1980/81. Location - 7G log files.

D) Selected QC, CPCL and CPQA test results for gamma batteries - Location - 7G, ATC & CPCL Laboratory.

E) Raw material RI inspection records for 1980 components - Location - Bldg N archives.

F) MRR's from RI and Power Source Engineering for 1980 - Location - Plant 7G and 7B MRR storage.

G) IHT's (Hold tags) from PSE for 1980 - Location - Plant 7G archives.

H) Microfilm records of several DCN's issued during suspect period - Location - ATC Microfilm archives at Documentation Control.

I) Bldg M production log books, where available -

I) Bldg M production log books, where available -
Location - Plant 7G.

J) Purchasing records for selected Gamma components -
Location - ATC Purchasing files.

Due to a lack of firm correlation, the search was terminated at Gamma lot 3780.

AUDIT SUMMARY OF FINDINGS

My review of the above documents failed to identify any defined cause for the Gamma battery failures. No firm correlation was found in use of components, MRR dispositions, or test results involving Gamma batteries produced in 1980, which could explain all of the high risk lot failures.

Review however, did find that the manufacture of Gamma cells during 1980, particularly during the middle of the year, was in a questionable state o control. Manufacturing was in a state of flux, with frequent changes bein implemented in such areas as component preparation, cathode powder mixing processing parameters, test measurements, etc. Over 100 incidents of specific anomalies in processing, equipment breakdowns or test results we documented by this audit. The more significant will therefore be presente below. Further review of these anomalies may suggest a possible failure mechanism.

A correlation was discovered between high risk battery lot numbers and Op sheet/drawing revisions. Over 65% of Gamma batteries experiencing Early depletion, cluster between lots 2180 and 2980. Based on data review, a major revision in Op sheets occured in Bldg M battery area, beginning wit Battery lot 2180. Revisions were reportedly made to the methods of electrolyte filling, burn-in, cell assembly, lid welding and lid assembly, among others. Further discussion will be presented below. The significance of the changes has not yet been identified and should be further investigated.

In addition, my review found that experimentation was being done to Production gamma cells during 1980 that was not called for in approved Op sheets. Cells were subjected to double burn-in, used re-fired cathodes, used experimental cathode formulations, etc. Many of these cells were subsequently released to pacer use and in fact, 5 "experimental" cells are included among the failed field returns recently received.

Evidence was also found that our vendors changed some of their processing parameters during the critical period of 1980. For example, I found that beginning with lot 2180, our gamma battery can vendor began washing gamma cans in Diversey Passivating solution. CPCL evaluated such solutions a f months later for possible use at Cordis but found them unsuitable. Our feedthru vendor suddenly began adding a letter suffix to its vendor lot numbers in mid 1980. Those feedthrus were first put to use in Gamma lot 2280. The reason for the change has not been identified. It may however suggest a change in a feedthru raw material which Cordis is unaware of. According to RI receiving records, the copper powder used to make cathode for gamma lots 2280 - 3380, came from a different copper Ingot manufacturer. The significance of the change should be further evaluated All significant references will be presented below.

DETAILED FINDINGS BY CATEGORY

PART A - COMPONENTS AND COMPONENT USAGE

In an effort to identify if the high risk lots shared a common raw material, the lot numbers for all principal components of the gamma batte were extracted from the batch records. This search covered Gamma lots 10 to 3680 inclusive. Battery lots 3780 on, were not reviewed in detail.

A total of 18 components were selected for coverage to include:

1. Cathodes used in each Gamma cell lot
2. Cathode powder lots used
3. The principal ingredients of each copper powder lot
4. Lithium
5. Electrolyte
6. Current Collector
7. Terminal Lid Assembly
8. Feedthrus used in the terminal lids
9. Lids
10. Backfill tubes
11. Gamma cans
12. Pellon .022"
13. Pellon .008"

In general, it was found that a typical Gamma cell lot number such as 2680 actually consisted of several sub-lots (Suffixed A through E). These sublots were all made in the same week, i.e. - week 26, but on different days (A = Mon., B = Tues., etc). Thus, Gamma lot 2680D would have been mad on Thursday of the 26th week. Review found that the sublots routinely differed from one another in the components used. Lot 2680 for example, used 5 different lots of cathodes, 2 separate powder lots, 3 feedthru lot 6 lid lots, etc.

Extensive review of component lot numbers, found no significant correlati between lots used and high risk battery lot numbers. Exhibits 2 - 13 cha these values. As can be seen, components used in the high risk lots were not used in all of the lots, or were also used in non-risk lots. For example, analysis of depleted cell field returns found that the pellon separators were of questionable quality. Review of Exhibit 9, however, finds that those same separator lots were present in numerous other gamma lots, none of which have failed.

Specific anomalies in some components were identified during this audit. They will be referenced in the sections below:

CATHODE POWDER MANUFACTURE & ANOMALIES

I next examined the available records covering the copper powder used in 1980 cathodes. Specifically, an attempt was made to identify if the quali of the powders correlate with high risk battery lots. The moisture, % fr sulfur, % soluable sulfates & Ph of each powder lot used in 1980 was firs charted. Exhibits 3 - 5 plot the results. No correlation can be identified. I did note however, that the level of sulfates in the cathod powder may have some impact on the length of time a battery will survive. Review of Exhibit 4 will show that lot 2980 and 3080 had soluable sulfate levels over 300% higher than other gamma lots. A total of 4 batteries ha depleted in lot 2980, all failing before the 15th implant month. The 2 failures recorded for lot 3080, failed before the 26th month. In contras failures from other gamma lots are averaging 30+ months before depletion.

The Ph of the cathode powders was recorded in Bldg. M log books, but shoul not be considered accurate. The operation used Ph 1-12 color change test paper. This paper gives only a rough estimate of Ph and in fact, when Bl M installed a Ph meter in mid-1980, my comparison of recorded results fou a difference between meter and paper values of > 1.5, for the same powder.

The number of water rinses that copper powder received during 1980, held steady at 5 rinses per batch until July. Beginning with the powder used i Gamma lot 2780, PSE began experimenting with rinsing the powders from 7 t 9 times per batch. Exhibit 6 plots these values.

The amount of rinse time the copper powder received during washing was plotted next. Although this time varied from 100 to 300 minutes, no correlation was found between rinse time and high risk gamma lots. (See Exhibit 6).

The amount of time cathode powders were dried in the vacuum cylinder, was examined. Drying times varied from 15 hours to 24 hours but again, no correlation was found. (See Exhibit 6).

CATHODE ANOMALIES:

* According to RI records, our supplier of copper dust, Gold Leaf Powders, changed its vendor of raw copper ingots in mid 1980. Starting with copper lot 122156, which was used in Gamma cells 2280 to 3380, the copper from which our dust was made came from a different vendor. Cordis QA examined this new copper lot, found no unusual anomalies and released it for use. The significance of the change is not known but according to CPCL personnel, copper dust is formed electrolytically by dissolving raw copper ingots and precipitating it out. Differences in ingot quality or purity could have an effect on the final particle size of the dust.

* According to MRR 70580 dated 6/3/80, the Hydrochloric Acid used in Gamma lots 1080 through 2580, was found to be "contaminated", after the fact. All remaining stocks of the acid were placed on the MRR in June and ordere scrapped. The MRR does not state what the "contamination" consisted of.

* Equipment problems were noted in the cathode powder log book, throughout 1980. Of significance is the following:

  1. At least 4 powder lots had to be discarded because the powder drying equipment broke down.

  2. The log shows that the deionized water filters clogged at least 4 times during 1980 and had to be changed. One such clogging occured i the powder used in Gamma lot 2480. The powder is repeatedly rinsed i this water. Clogged filters indicate precipitate buildup and may allow minerals such as calcium, magnesium, etc. to be incorporated into the cathode powder. The significance of this has not been fully studied.

  3. Another recurring problem involved rust corrosion in the drying cylinder. On two occasions, powder production was interrupted becaus of drum corrosion. On each occasion, the drum was sent to maintainance for re-passivating in Nitric acid. Copper Powder used i Gamma lots 2280 and 2380 is involved.

* The log contains entries stating that on at least 2 occasions, the coppe powder was found floating on the top of the rinse water during washing, an would not sink. Both entries involve powder used in Gamma lots 3280 & 3380. This anomaly may indicate a problem with particle size of 1980

cathode powders. Particle size was not measured during 1980 but if too fine, copper particles could permeate the battery separator during use. This is precisely what has been found in the bulk of the returned gamma field failures.

* Based on records, Bldg M production had a significant variation in th of cells, without explainable cause. Powder lot G0680 was reportedly m the same as all other powder lots, but when tested, was found to have a of 2.5. The lot was discarded. CPCL was then asked to examine samples cathodes made from powder lots G1080 and G1480. (Neither powder lot was used in production). Examination found both lots to be similar with tw anomalies noted. Both lots had a Ph of 3 yet the copper powder log lis the Ph of the powders as 4.3 & 4.6 respectively. No explanation for th drop in Ph was offered. Secondly, both samples had a "skim" layer of Cuprous sulfide on the cathode surface. (See CPCL Report 23-02039 for further details).

* CPCL Report 23-02018 (Exhibit 15), examined the purity and content of copper powder lots G1080 and G1480 themselves. Samples from these lots were reportedly held under different atmospheric conditions, as an experiment. The Report results are seriously anomalous. The moisture content of one sample held under "very dry vacuum" was found to be 250% higher than the moisture of samples held under 100% humidity. Sulfates free sulfur were also not as expected. Either the samples were inadvertantly mixed up, or the vacuum lines, glove boxes and argon supp at Bldg M was questionable. Continued searching found further evidence this possibility. A CPCL test was performed in June/80 on the atmosphe of the gamma assembly glove box. (CPCL Report 23-01890) Two samples w collected two weeks apart. It was found that the oxygen content of the argon glovebox increased from .024% in May to .16% in June, a 660% increase. Likewise, the moisture content of the glovebox increased fro .005% to .015%, a 300% increase. This suggest a leak in the glovebox. Under these production conditions, which represent the time period of highest risk cells, the chemistry of the cell interior may very well ha been affected.

* According to records, Bldg M had both a DI water line and a Distilled water line feeding the powder room. Log indicates that some powder lots used distilled water; others used DI. The significance of this is not known.

* MRR review found that the sulfur used to manufacture all copper powder from January, 1980 to at least September/80, was material received in mi 1979. In April/80, this Sulfur expired and was placed on MRR. No other supply was available so a sample was sent to CPCL, found to have an acceptable melting point and was released UAI with a 4 month extended sh

life. In Aug/80, it expired again and was released UAI again, after another melting point sample found no problems. The significance of using aged sulfur should be explored further.

* In Aug/80, PSE requested that argon or nitrogen gas be bubbled through the DI water used for rinsing copper powder, 1/2 hour prior to use, to "deairiate" it. It is not known if this additional change altered the quality of subsequent powders produced.

* As will be discussed later, portions of a few Gamma cell lots were experimentally produced with Dry Cathode Powder, the method we used to ma powders in 1979. Some of these cells were subsequently released for pace use. To date, however, none of them have failed in the field.

GAMMA CATHODES & ANOMALIES

The quality and manufacturing conditions involving cathodes used in 1980 gamma cells was next examined. Over 90 separate lots of cathodes were manufactured during 1980. No one lot was used in more than 3 Gamma battery lots. No correlation can therefore be made. Data regarding cathodes used is on file at Regulatory Affairs.

Cathode weight and thickness were examined. The cathode weight varied by no more than .02 gms throughout 1980. No correlation was noted. Cathode thickness did vary to a greater extent. 10 of the 27 lots of cathodes use in Gamma cell lots 2180 through 2980, were found to be below spec for thickness and were placed on IHTs. The cells were nevertheless released UAI. This is a significant correlation in component parameters since lots 2180 through 2980 are the highest risk gamma lots. Review of other 1980 gamma lots experiencing failures, however, finds normal cathode thickness values. The correlation is therefore reduced.

* The records I reviewed, contain several additional references to cathode anomalies. IHT records show that virtually every lot of batteries produced from 1080 to approx. 2880, suffered cell swelling problems. This generall indicates excessive moisture in the cell, usually from the cathodes. The moisture content of fired cathodes was not measured in 1980, however and a extensive search of archives failed to locate the critical cathode fire oven temperature charts for 1980. A positive correlation between cathode firing/moisture and high risk gamma cells, cannot therefore be made.

* 1980 cathodes were found suffering from cracking, prompting a study to b done by PSE in July/80 on the effects cracked cathodes have on OCV readings. I failed to find additional references to the problem during

record review, however, and the true extent of cathode cracking in 1980 gamma cells is therefore not known. According to CPCL study results, cracked cathodes do not appear to have a significant impact on cell life.

* Power Source Engineering experimented with the firing of cathodes durin 1980. At least 3 references were found in Production gamma cell records showing portions of lots 2180B, 3280, 3380 and others, contained cells wi re-fired cathodes. Numerous experiments were conducted during the middle of 1980 into refiring the cathodes, in an attempt to reduce negative voltage drops which the majority of the 1980 lots suffered. My review found that most of these refired cells were released eventually to pacer use, after long term monitoring found no significant anomalies. It should be noted that one of those cells was among the field return failures received.

LITHIUM USE & ANOMALIES

Review of lithium use in 1980 Gamma cells found no firm correlation. (See Exhibit 7). A total of 11 Lithium lots were used between 1080 and 3680, but extraction of the vendor lot numbers from RI archives found several of them to be of the same vendor lot. In actuality, only 5 vendor lots of lithium were used. Each lot was examined visually by RI upon receipt, each was accompanied by a Certificate of Analysis and no anomalies were noted by RI. One vendor lot (P04010317) was used in Gamma lots 2180 through 3080, the highest risk period, but its use would not explain battery failures in the other Gamma lots.

The records do indicate however, that on several occasions, the Use before date of the lithium stored in bldg M expired. On each occasion, the lithium was placed on MRR and a sample visually examined by Bldg M QC. In all cases, the samples were found bright & shiny and the Use Before date was therefore extended. No correlation was found.

* On 7/22/80, 400 wafers of lithium lot 124343, stored in open cans in the Bldg M argon glovebox, were placed on MRR 82001 because all 400 wafers were found blackened. MRR disposition was scrap. No explanation for the blackened lithium was given, but it strongly suggests a glovebox leak. Of significance, however, is the fact that Lithium lot 124343, is vendor lot P04010317. As reported above, this vendor lot was used in Gamma cells 2180 through 3080, all of which are suffering significant field failures.

ELECTROLYTE USAGE AND ANOMALIES:

Exhibit 8 is a plot of electrolyte usage during Gamma battery manufacture from Gamma lot 1080 to 3680. Review finds no significant correlation. A total of 9 vendor lots of electrolyte were in use, with no lot used in mo than 6 weekly lots of Gamma cells. During the high risk Gamma cell perio between gamma lots 2180 and 3180, 5 separate lots of electrolyte were use

Record review found, however, several anomalies pertaining to electrolyte, with the following judged to be most pertinent:

* MRR's 79346 & 79347 dated 7/7/80, ordered 41 cells from Gamma lot 2180 and 37 cells from lot 2280 scrapped, due to "electrolyte contamination & helium leak test". No specifics were given to explain the reference to electrolyte contamination. It should be noted that the period of highest risk Gamma cells begin with Gamma lot 2180.

* Based on MRR review, precipitation of electrolyte salts while in storage bottles was occuring during 1980. In two cases, the electrolyte was reworked by filtering/settling, retested and found to be acceptable for continued Use As Is. In a third case, it was ordered scrapped. (The scrapped lot was never used in production).

* CPCL Report 23-01849, dated May/80, detailed a study done on several cells from Gamma lots 1480 to 1880. These samples were collected by PSE due to a high number of - Delta voltages seen in these lots (up to 90% of some lots had a decrease in voltage between 1st & 2nd OCV readings). CPCL found in part that cells experiencing negative delta's, had very low levels of polymerizations of the Polydioxolane portion of their electrolyt (1.4mg) while cells which had experienced + delta's had polymerizations averaging 18 mg., a full magnitude higher. Why the differences existed wa not explained.

* A study was done in November/80 to determine why electrolyte discolors after 24 hour burn-in. CPCL Report 23-02129 revealed that the discoloratio may be a decomposition product of the Dimethylsoxazole portion of the electrolyte. The report did not explain if discoloration was a serious problem during 1980.

* Exhibit 14 details a series of revisions made to Operation sheets & drawings during 1980. Beginning with Gamma lot 2180, the Op Sheet for Electrolyte Filling (OPS M-318-014) was changed from Rev. 2 to Rev. 3. What this change details has not yet been determined but should be further investigated. This new revision was used from Gamma lot 2180 on.

PELLON SEPARATOR USAGE AND ANOMALIES:

Pellon separator material is strongly implicated in the current Gamma depletion problem. The majority of failed cells contain separators that are permeated with copper salts, providing a potential conductive path between cathode and anode. Pore size of the separator is of significant importance but unfortunately, pore size was not an RI measurement in pell material used in 1980 and data is lacking.

My review of records involving Pellon finds no correlation between Pellon lots in use and Gamma high risk cells. Exhibit 9 plots such usage. As ca be seen, only one lot of Pellon .008" separator was used between Gamma lo 1080 and 3580. If this lot was defective, problems should be appearing i all Gamma cells, which is not the case.

5 lots of Pellon .022" separator were used during the period in question. The division from one lot to another appears unrelated to high risk Gamma cell failure patterns.

According to routine processing, pellon separators are supposed to be stored for 48 hours in an argon filled vacuum chamber prior to use. Bldg did not, however, keep any records of this processing step and a determination of whether this step was performed each day cannot be made.

In 1980, the separator material used in the Gamma cell was the same as wa used for crimped D cells. In order to achieve a proper fit, Pellon separators for Gamma cells had to be cut with scissors by hand. There is no written record of this processing step either. Whether handling and manipulation of the separators in this manner could have contaminated the or affected their performance, should be discussed further.

A series of anomalies involving the Pellon Separator were noted in my review of records:

* CPCL Report 23-01815, attached as Exhibit 16, reports an analysis performed on one cell from Gamma lot 1780. The sample was sent to CPCL b Bldg M after an "orange discoloration" was noted on the separator materia (I presume this discoloration was noticed before the cell was sealed). CPCL found that the pellon in this cell contained iron particles "dispers as aggregates throughout the separator material". The cathodes in the ce appeared "normal", with no iron contamination noted. How the iron got to permeate the separator, or where it came from, was not documented. Anoth reference to "particles" in separators is Service Request 5249 dated 5/20/80, which requested CPCL to identify the "wavelike particles" lined i the middle of an unidentified separator. The study was cancelled for reasons not specified.

* During the middle of 1980, numerous Gamma cells were submitted to CPCL for teardown analysis, in an attempt to evaluate the negative delta problems Bldg M was experiencing. Several of these cells were purposely discharged or had failed accelerated testing. As part of these tests, C examined the separators. Their results are interesting:

a) CPCL Report 23-01884 dated 6/10/80, details analysis of one cell from lot A1780 that had self-discharged at 90 degrees C. Part of th findings include an observation that the separator was found permeat with particles of CuS, right to the vicinity of the anode. This suggests that permeation of separators with copper was occuring to very early 1980 Gamma cells.

b) CPCL Report 23-02076 analyzed 3 cells from Gamma lot 1280, that h been subjected without load to different experimental temperatures. The cell stored at 54 degrees C, had self discharged with only 28% Lithium remaining. In addition, all 3 cells had "copper migration into the separator". This again is significant because Gamma lot 12 is not considered a high risk lot (no field failures). Perhaps that is due not to the quality of the lot, but to the fact that only 21 pacer implants with that lot have occured.

c) CPCL Report 23-01849 dated 5/6/80, examined cells from lots 1480 1880. Review found many of the separators to have black trails of material crossing the separator surface at the anode interface. The material appeared to be copper sulfide. Also found was a waxy "laye of material discoloring the separator, again at the anode interface. Analysis found this to be a lithium polysulfide material. According to the report, cells having no negative delta problems also had no waxy layer present on the separator. This finding could not be explained.

TERMINAL LID ASSEMBLY
BATTERY LIDS, BACKFILL TUBE, FUSITE FEEDTHRU AND GLASS INSULATOR

Extensive review of the records associated with the Gamma terminal lid assembly was undertaken. The terminal lid assembly in 1980 was manufactured by Cordis from components purchased through vendors or produced by the Cordis machine shop. The assembly consisted of a battery lid with welded ferrule, a stainless steel, nickel coated feedthru wire surrounded by a glass insulator and a stainless steel backfill tube.

The lid and backfill tube were produced by Cordis Plant 2. A parent order was filed and assigned a job number such as "H5063". Each day, a portion of that order was produced by Plant 2 and assigned a sub-lot number. For example, lids produced one day might be lot coded H5063-5. Lids produc the next day would be coded H5063-6, etc. If the steel raw material fr which the parts were made changed, the job number would change.

Review of records finds that Bldg M utilized two lots of steel in the l used in Gamma lots 1080 through 3680 and 4 lots of steel in the backfil tubes. A total of 110 sub-lots of lids and 95 sub-lots of backfill tub were produced by Plant 2 for the period in question. Exhibit 10 plots usage in the Gamma battery. No significant correlation was noted.

The Feedthru and glass insulator were both purchased as a completed unit from Fusite Div., an outside vendor. Fusite assigned a two digit lot nc to each shipment of the above. Upon receipt, Cordis assigned its own Cordis lot number. Again, review of lot records found no correlation between Fusite lot numbers and high risk Gamma battery cells. Exhibit 1 plots these values. A total of 37 Fusite lots of Feedthru Insulators we: used in Gamma lots 1080 through 3680. No one Fusite lot was used in more than 3 Gamma battery lots.

One potentially significant correlation was noted, however, in the Fusite lot numbering code. All of the feedthrus used in Gamma lots 1080 to 2180 had only a 2 digit Fusite lot number (i.e. - 18). The feedthrus used in Gamma lots 2280 on, however, show a 2 digit lot # plus the letter suffix, "F". (i.e. - 20F). I have not been successful in identifying the significance of this change in the Fusite lot #, but did determine that Fusite Div. made the change, not Cordis. Changing a lot code system, usually denotes a change in material or processing method. If Fusite made such a change, perhaps without our knowledge, the significance of it may b of some importance.

* Related to the above is another observation of note. Fusite Certificates of Analysis accompanied each Fusite lot. On those certificates, Fusite recorded their part # for our feedthru and the lot number of something called the "V Blend". My review found that for all of the feedthrus used in Gamma cells 1080 to 2080, the part # listed on their certificate was 41-X3895. The feedthrus used in Gamma cells 2180 to 3680, however, had the part # listed as 41-61503. This is highly significant since 2180 begins the high risk Gamma lots. Similarly, the Certificates show that V Blend Lot # "Eng. 1", was the lot used in feedthrus found in Gamma cells 1080 through 3380. I then noticed a change. The feedthrus used in Gamma cells 3480 on, reportedly contained V Blend lot # "100". It may be argued that Gamma lot 3480 marks the end of the high risk Gamma cells. This change may therefore be of significance, and I suggest it be pursued further.

ANOMALIES:

Fusite feedthrus and insulator glass are also implicated in the current Gamma battery depletions. Lab analysis has found a significant corrosion of the glass in many of the failed cells. Consequently, anomalies regarding the terminal lid were examined closely, and the following is offered:

* CPCL Report 23-01884 dated 6/10/80, reports on an analysis of a Gamma cell that had self-discharged at 90 degrees C. Analysis found in part that:

a) A white deposit containing calcium, silicon and aluminum was found on the interior lid surface, while an iron rust deposit was found at another lid location. The conclusion was "lid corrosion due to possible acidic environment."

b) Crystals of lithium perchlorate were found on the feedthru and feedthru glass resistance was quite low.

* CPCL Report 23-02003 dated 8/80 and Report 23-02015 dated 9/80, found that cells from Gamma lots 1680 & 1580 respectively, contained rust and flaked steel on the inner lid surface, indicating a lack of adequate passivation. This is similar to item (a) above and may indicate that our Gamma lids during this period were not receiving adequate passivation. The consequences of this for long term survivability of the cell should be explored.

* Copper contamination on the Fusite Feedthru and the Cordis lid was noted in several records which I reviewed. At least 4 MRR's ordered Feedthrus or lids scrapped due to copper. How the copper got on the parts, was not explained. As examples,

a) CPCL Report 23-01818 dated 5/7/80, details findings of an attempt to remove copper from one lot of Cordis lids by bathing the lids in Nitric acid passivating solution. Some copper remained, however, and the lids were scrapped.

b) MRR 79290 dated 4/22/80, quarantined terminal assembly lots D0280 & D1080 due to "copper contamination" on both sides of the lid. According to the MRR, final disposition was not made until 12/80 with both lots ordered scrapped. Yet according to Gamma cell production records, Terminal lid lot D0280 was used in 242 cells of Gamma lot 1780. Terminal Lid lot D1080 was used in 340 cells of Gamma lot 1880. To date, 2 of those cells have failed in the field. Copies of the pertinent documents are attached as Exhibit 17.

* Cracked glass in the Fusite Insulator was perhaps the biggest problem facing Bldg M during 1980. Based on records and personnel, the quality of the glass was very poor. Due to a shortage of parts, however, Bldg M continued to use the Fusite parts after 100% sorting. Nevertheless, my review finds that poor glass insulators were used in Gamma cells. Specifically:

1. At least 5% of every lot of Gamma batteries produced in early to mid-1980, was scrapped for cracked or leaking glass.

2. Over 20 MRR's or IHT's were generated to address the problem, covering feedthrus used in Gamma lots as early as 1180. Gamma lot 1980 had over 100 cells quarantined on IHT 28050 for "cracked glass with evidence of electrolyte leakage".

3. MRR's 76837 and 76863, dated April/80, placed all pieces of Feedthru lots 10, 11 & 12 on MRR because they had failed the glass insulation resistance test. Disposition was U.A.I. with no further explanations. These feedthrus were used in Gamma lots 1780 through 2180.

4. CPCL Report 23-02013 analyzed a cell from Gamma lot 1680. 32% of the glass had been corroded away.

5. CPCL Report 23-02032 reviewed Fusite glass composition. Results found that the ratio of Potassium to Barium in unused glass, was opposite the expected formulation ratio of 2:1 Ba to K.

6. MRR 80109 dated 6/13/80, dispositioned 4 lots of rejected Fusite Feedthrus. MRR 80165 dispositioned 3 more lots. All seven lots suffered visual glass cracks, glass cross-sectioning & feedthru electrical resistance failures. In addition, Feedthru lots 24F-27F had a glass density below the Cordis spec. MRR Disposition was UAI and reads in part, "Resistance failures due to residual salts. Bldg M to clean before use." These feedthrus were subsequently used in Gamma lots 2380 - 2680. These are the highest risk Gamma lot currently on file, with over 60 field failures to date. How the feedthrus were cleaned or if in fact they were, is not detailed on the MRR's.

7. MRR 70595 dispositioned several cells that had been quarantined for "cracked glass" or "copper on glass". Gamma cell 097 of lot 2680A, was one of those cells. It was dispositioned UAI. Cell 97 is one of the cells that failed in the field.

8. CPCL Report 23-02076, analyzed 3 cells from Gamma lot 1280 that had been held at elevated temperature. Part of the findings was a marked decrease in resistance of the fusite glass in all 3 samples. One cell's feedthru glass had a resistance of only 67000 ohms.

9. IHT 28047 dated 8/7/80, quarantined 15 cells from Gamma lot 1180 for cracked glass and "brown contamination" on the exterior lid. Disposition was to wash in acetone, quarantine 24 hours than UAI. Brown contamination may suggest electrolyte leakage through the "cracked glass". If this "rework" procedure was used throughout 1980, a number of leaking cells may in fact have been released, sin washing away the stains does not stop leaks.

Additional CPCL findings regarding glass corrosion are on file with the Gamma task force.

* CPCL Report 23-01946 dated 7/16/80, analyzed a foreign particle found b Bldg M on a Fusite feedthru during cell assembly. The particle was identified as brass. How it got there was not explained.

* Service Request 5347 dated 6/80, requested CPCL to identify some white powder found on another Fusite feedthru. Analysis identified it as Zirconium.

* CPCL Report 23-01977 dated 8/4/80, examined the steel in samples of the Cordis lid and the Fusite feedthru. A strict specification requires the Fusite feedthru to be made out of 426 Stainless Steel with nickel plating CPCL found the feedthru was not 426 S Steel but an iron nickel alloy of unidentified nature. The significance of this for long term cell survivability should be further evaluated.

* The revision level for the Gamma feedthru drawing, changed during 1980. From Gamma battery lots 1080 to 1680, it is listed as Rev. 1; from Gamma lot 1780 to 2080, it's listed as Rev. 4. Gamma lots 2180 to 3680, list i as Rev. 5. Specifically what changed in this part, has not yet been determined. Note again, however, that 2180 is the beginning of the highe risk period. In addition, beginning at Gamma lot 2180, the Revision leve of the Terminal Feedthru assembly itself reportedly changed from Rev. 3 t Rev. 1. This is based on the Rev. level entries recorded by operators wh filling out the Gamma Batch Record. This does not make sense however, since a movement backward in revision levels is unexpected. Further, the route sheet for the terminal lid, still lists it as Rev. 3 throughout mos of 1980. Either the operators made a mistake in recording, or they were using an obsolete drawing or component.

* Likewise, a major revision of Operation sheets is recorded as taking place, beginning with Gamma lot 2180. One of those Op sheets, M-318-017, changed from Rev.2 to Rev. 3. This Op sheet details how to weld backfill tubes. Details of the change have not yet been identified.

* Service Request 5507, asked CPCL to examine some experimental gamma lid and actual cells that had been assembled with Northeast Corp. Feedthrus & glass. Two assembled cells from Gamma lot 3480 (cell 453,454) were submitted. CPCL Report 23-02038 dated 9/10/80, found that the "Northeast glass" in the 2 cells from Gamma lot 3480, was smooth, shiny and had a better appearance that Fusite glass. Both documents are attached as Exhibit 18. Based on my followup of this matter, however, there is absolutely no record of Northeast feedthrus or glass ever being used in Gamma lot 3480, and in fact, no record of Cordis ever purchasing feedthrus/glass from Northeast until 1981. If the CPCL report is accurate then Power Source Engineering built experimental cells from Gamma lot 3480 with Northeast glass from an unknown source, without telling anyone. Whether other Gamma lots contain this material, has not been identified.

* A variety of Service Requests, DCN notes and IHT's mention annealing of terminal lid parts as a concern. According to personnel, Cordis sent terminal lids to outside vendors for annealing in hydrogen gas. The method or thoroughness of annealing has not been examined but based on the MRR's IHT's encountered, it was not uniform. For example,

a) MRR 70547 ordered 31 cells from February Gamma production scrapped, because of "unannealed terminal lids".

b) MRR 81287 scrapped 15 assorted batteries from lots 2380 through 3880 because the feedthrus did not take the solder. This may indicate an annealing problem.

c) CPCL Report 23-01752 examined samples of experimental backfill tubes that were annealed before welding. The welds were found unacceptable.

The consequences of using terminal lids that had not received proper annealing, may be an avenue for further discussion.

CURRENT COLLECTORS & GAMMA CANS

Use of Anode Current Collectors in Gamma cells was plotted, and no correlation was noted. Exhibit 12 shows these results. Although one principal lot of current collector was used in high risk cells, a differ lot was used for Gamma Battery lots 2280, 2380 and 2980, all of which sh field failures.

10 different lots of battery cans were used from Gamma lot 1080 to 3680. correlation was found when lot numbers were plotted (See Exhibit 13).

Several anomalies regarding cans or collectors were noted:

* A total of 5 pull tests were performed on anode/collector weld samples from Gamma lot 1780. 2 of these pull tests failed and all of lot 1780 w placed on MRR. Final disposition was UAI 124 cells, scrap 131. The sam for Gamma lot 2180B also failed weld analysis. Disposition was UAI. Failed welds strongly indicate an unannealed current collector. The collectors used in 1780, were also used in most of the other high risk gamma lots.

* According to a note found on a DCN in the archives, Gamma cans were not being passivated prior to mid-1980. Beginning with Gamma battery lot 218 the drawing was changed to require the cans to be annealed and then passivated in "Diversey dip" solution by our outside can vendor. My further research revealed that Diversey solution is not a passivating agent. It contains Hydrochloric acid, which destroys any passivation lay which might form. CPCL Report 23-02052, documents this conclusion and recommends against use of Diversey solution by Cordis. In addition, the report states that Diversey solution contains a surfactant. Since Gamma lot 2180 begins our high risk lots, the consequences of using Diversey di on the gamma cans should be explored further.

* Several MRR's found specific lots of Gamma cans or collectors to be out of specification for dimension or visual finish (nicks, burrs, etc.) In most cases, the disposition was "UAI", although one lot of collectors was ordered Returned to Vendor for "visual contamination". What the contamination was, was not specified.

PART B - GAMMA BATTERY PRODUCTION

Review of the over 5,000 pages of production records covering Gamma lots 2180 through 3680, found numerous anomalies and trends, but no firm correlation which could implicate a manufacturing condition as the Early Battery depletion cause. In particular, Gamma lots 2480 and 2680 were examined in extensive detail. These two lots alone, account for over 36% of all field failures to date.

Processing conditions varied throughout 1980. As previously discussed, changes in component handling were documented but in addition, weld parameters were altered, equipment breakdowns forced delays and Engineerin instituted numerous experiments with production cells. I was unable, however, to demonstrate that all high risk lots shared the same anomaly in processing. For your information, the following are the most significant processing anomalies noted:

The greatest single anomaly in 1980 Gamma production was the appearance of negative delta voltages. Gamma lots from January/80 to approximately 4580, suffered varying amounts of decreases in the voltages of their cells, in the span of one week. In fact, the appearance of negative deltas wildly fluctuated within the same weekly lot. For example, 75% of lot 3180A and 79% of 3180D had voltage drops while less than 10% of 3180B & C had them. Unfortunately, the negative delta trend does not correlate with long term cell survival. For example,

a) Less than 5% of Gamma lot 2680 experienced a Negative delta problem while approximately 34% of Gamma lot 2480 suffered from it. These are the two highest risk lots of 1980 production.

b) Over 90% of Gamma lot 2780C suffered voltage drops of from 1 to 4 millivolts in one week, while 2780D had a 60% negative delta problem.

c) 30% of all cells in Gamma lot 1680, 25% of Gamma lot 1780, and approximately 20% of lot 1880 suffered negative delta. Yet there are no recorded field failures from Gamma lot 1680 to date. Additional examples can be cited.

gardless of the cause, Bldg M was not able to eliminate the problem during 1980. Fully 40% Of 1980 production as far forward as Gamma lot 4580 was quarantined on a voltage monitoring program while extensive efforts were conducted to identify if negative delta affected the life of the cell. All test results found no significant impact on cell performance. The vast majority of the cells increased in voltage eventually and stabilized at a voltage within specifications. Most negative delta cells were eventually released for pacer use. I should note however, two points of concern. First, the monitoring program apparantly was not fully successful. Two MRR's were found which quarantined cells with negative delta, that had been released from the monitoring program and shipped to Plant 7, only to be returned due to the re-appearance of voltage drops. (MRR's 80972 and 78383). Secondly, at least 8 cells which did have negative delta at one time but were released for pacer use, suffered early depletion and are among the gamma field returns.

* In addition to Negative delta, numerous 1980 Gamma lots also suffered from low voltages below the bottom limit of 2.132 V. Again, wide swings in voltage were noted within the same weekly lot or adjoining lots. For example,

> a) 47% of the cells in Gamma sub-lot 2880B and over 60% of sub-lot 2880E experienced low voltages and were quarantined on MRR. Yet sub-lots 2880C & D demonstrated more normal voltages, with few falling below the limit.
>
> b) 80% of the cells in Gamma lot 2780 suffered low voltages and the whole lot was placed on monitoring. Yet the voltages found in cells from a few weeks before, were normal.
>
> c) The average voltages seen in Gamma lot 3080E were in the 2.139 V range. Yet a day later, the cells from sub-lot 3080F had average voltages of 2.154 V, significantly higher.

As was the case with negative delta, the majority of these low voltage cells increased to a stable voltage level within specification after long term monitoring and were eventually released. Again, I note that at least 2 of these cells failed in the field.

* The last principal trend of note regarding 1980 Gamma cells, was a problem with cell swelling. Over 10 MRR's disposition cells from Gamma lots 1280 to 2880 for excess cell thickness. 27% of Gamma lot 1180, 35% of lot 1480, 16% of lot 1580, 40 % of lot 2880 and over 90% of Gamma sub-lot 2780C experienced swollen cells and had to be rejected. Based on record review, however, the swelling of cells does not appear implicated in the early depletion problem. Lot 2680, the worst high risk lot to date, had only 15 or so swollen cells in the entire weekly lot.

Again, the cells were placed on monitoring and eventually shrunk in thickness to within specification. A cross review of cells released from monitoring and field failures, found no examples of previously swollen cells depleting in the field.

* As part of the major revision to Op sheets which occured at Gamma lot 2180, one of the changes was to OPS M-318-020, which is "Start Burn-in". Exactly what the change was, has not yet been determined but if burn-in parameters or methods were significantly altered, it would directly affect the amount of lithium present in the cells upon shipment to pacer line.

An additional variety of equipment breakdowns or anomalous occurances we noted in review of the records, but there is no pattern. References include such notes as "high humidity in room today", "oven broke down, "drying drum corroded & sent for passivation", "batch discarded - pilot cells failed", "welder not qualified", etc. IHT 26018 dated 3/7/80, quarantined 7 cells from an unidentified lot because the "cells were bur in with 2K resistors. Spec requires 2.2K". This suggests a possible wir· mixup.

EXPERIMENTATION:

Experimentation with production Gamma cells was occuring during 1980. Although the release to pacer use of experimental, unqualified batteries was a serious violation of GMP's, no direct correlation could be proven between experimental cells and early depletion failures. As examples:

a) Extended 48 hour burn-in of cells was performed several times during the summer of 1980, with production records listing at least references to 48 hour burn-in. After burn-in, the cells were place on monitoring schedule. If found acceptable, they were released for pacer use. Several of these 48 hour burn-in cells failed in the field and are among the Early Depletion failures, to include cell 6 of lot 3180A, cell 455 of lot 3280D and cell 961 of lot 3080E. The others are apparantly still functioning.

b) Numerous Gamma cells were sent by Engineering to the laboratory for Shock & vibration testing. After such testing, the cells were monitored. If acceptable, they were released for pacer use. 86 cells from Gamma lot 2580A and at least 10 cells from lot 2680, received such treatment before release. I did not determine whether any of these cells failed in the field, but the data is available through cross-referencing and may be identified if desired.

c) Gamma lots from 3680 through 5080, contain references in the batc records and in the Gamma shipment records, indicating that some of the cells in each batch were earmarked as "pilot cells". I was unable to identify specifically what was unique about them or what the pilot experiment consisted of, but over 500 cells are involved.

d) Three cells from Gamma lot 2580E were removed from Production just prior to electrolyte filling and fitted with a welded burn-in wire, then returned to the line. This experiment was an attempt to see if cells placed on burn-in at the instant of electrolyte filling, survived longer than normal cells. After 24 hours burn-in, the wire was removed and the cells were monitored. I could not determine if they were ultimately released for pacer use.

e) As previously mentioned, cathode dry powder was used in at least Gamma battery lots in Mid-1980. As an example, 65 cells from Gamma lot 3380, received dry copper powder cathodes made experimentally. Rather than retain these cells as experimental, however, Engineering & QC apparantly agreed to place them on monitoring and release them if found acceptable. I found reference to at least 35 of the cells being released for pacer use. Cross-reference check found that none of them are included in the field return failures to date.

The above details of experimentation were culled from available notes in the batch records. According to personnel questioned, however, additional experiments with production cells were occuring during 1980 to solve the negative delta problem. Not all of them may be noted on the records. Use of the Northeast feedthrus previously mentioned, is one example. My review of limited Engineering files revealed that some cells from an unidentified production Gamma lot were purposely "salted" with lids that had varying degrees of copper contamination, then examined by Engineering. The disposition of the cells is not noted and I found no reference to this experiment in actual Production records.
I therefore suggest that Power Source Engineering files from the period be examined in detail for further clues.

RECOMMENDATIONS:

Task Force review of the data in this report will hopefully suggest some further avenues of exploration for solving the question of what the causes of the Gamma early battery depletions are. In addition, I feel that the following approaches may also prove fruitful:

1. To more fully address the question of whether copper permeation of Gamm separators is mechanical and related to particle/pore size of the cathode separator, Engineering should examine a number of rolls of pellon currentl in stock. According to personnel, a single roll can vary in quality & por size from foot to foot. Remove from the rolls, selective sections of pellon which have large pore sizes or small pore sizes. Prepare a wet cathode powder lot with copper dust to the same formula and mixing parameters as used in 1980. Determine the particle size of the powder, form cathodes from it and build a group of experimental cells, using the large pore size pellon and another group with the small pores. Subject them to testing and compare their survival rate with the extent of copper permeation of the pellon. If a firm correlation is found, early battery depletions may be considered to be a mechanical failure mechanism. If no

correlation is found, it strongly suggests that there is a chemical failu mechanism at work.

2. If evidence points to a chemical failure mechanism, it can be due either to a contaminant in the cell or an unknown reaction of the existin components. An attempt should be made to identify if contamination is present, through a thorough elemental & chemical analysis of the contents of failed vs acceptable cells, to include cathodes, lithium, separators, electrolyte and feedthru/glass. I believe enough cells from 1980 production exist to carry out such a task.

EXHIBITS:

Copies of pertinent MRR's, IHT's, Batch records, CPCL Reports, etc. referenced in this report, will be retained in RA files for future reference. In addition, the following exhibits are attachments to this report:

1. Listing of "High Risk Gamma Battery Lots
2. Plot of Cathode Ingredients vs. Battery Lot #
3. Plot of Copper Powder Moisture vs. Battery Lot #
4. Plot of Copper Powder Soluable Sulfates vs. Battery Lot #
5. Plot of Copper Powder Sulfur levels vs. Battery Lot #
6. Plot of Copper Powder Processing Parameters vs. Battery Lot #
7. Plot of Lithium Usage vs. Battery Lot #
8. Plot of Electrolyte Usage vs. Battery Lot #
9. Plot of Pelion Separator Usage vs. Battery Lot #
10. Plot of Terminal Lid/Backfill Tube Usage vs. Battery Lot #
11. Plot of Feedthru Usage vs. Battery Lot #
12. Plot of Current Collector Usage vs. Battery Lot #
13. Plot of Gamma Can Usage vs. Battery Lot #
14. Plot of Op Sheet/Drawing Revisions vs. Battery Lot #
15. Copy - CPCL Report 23-02018
16. Copy - CPCL Report 23-01815

17a) Copy - MRR 79290 dated 4/20/80
17b) Copy - Production Route Sheet - Gamma lot 1780
17c) Copy - Production Route Sheet - Gamma lot 1880
18a) Copy - Service Request # 5507
18b) Copy - CPCL Report 23-02038

Ex. #45
EIR 12/3-22/83

[illegible] copy [illegible] Destr 10/10/[illegible] 9/30/[illegible]

REGULATORY AFFAIRS
AUDIT REPORT DISTRIBUTION LIST
DO NOT REMOVE FROM FILE

EIR CORDIS CORPORATION
12/3-22/83 VB/ELJ
EXHIBIT 45 PAGE 1 OF 1

AUDIT X
POST-AUDIT ______
AUDITOR
DATE ISSUED 9/22/83
TITLE Special Audit - Gamma Battery Cell Depletion

IMPLEMENTATION PLAN DISTRIBUTION:

COPY NO.	INDIVIDUAL	DATE RETURNED	DATE DESTROYED	OTHER
1	* Cordis Employee	9/29/83	9/29/83	
2	Cordis Employee	9/30/83	9/30/83	
3	* Cordis Employee	9/26/83	9/26/83	
4	* Cordis Employee	9/27/83	9/27/83	
5	Cordis Official	9/27/83	9/27/83	
6	Cordis Employee	10/10/83	10/10/83	
7	* Cordis Official	10/7/83	10/7/83	
8	Cordis Employee	9/28/83	9/28/83	
9	* Cordis Employee	9/28/83	9/28/83	
10	* Cordis Employee	10/3/83	10/3/83	
11	* Cordis Employee	10/24/83	10/24/83	
12	* Cordis Employee	[illegible]	To → OJ Orig Destroyed	10/10/83 MDA
13	Cordis Official	9/28/83	9/28/83	
14				
15	3 file copies	Destroyed —	mda 9/26/83	
16	1 (1st copy - [illegible])	1st 9/26/83	[illegible]	
17				
18				
19	* Rec'd Exhibits also.			
20	Others just audit report			

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Memorandum

11.0

DCB

Pls review this material + the [illegible] file. especially if [illegible] this and then lets disc

RECEIVED
NOV 7 11 32 AM '83
ORLANDO

Date November 1, 1983

From Division of Compliance Operations, HFK-116
National Center for Devices and Radiological Health

Subject Request for Investigation
Alleged Early Pacemaker Battery Depletion
Assignment #D984

To Orlando District, HFR-4250
Director, Investigations Branch

Firm: Cordis Corporation
Miami, FL

We have received a copy of a September 22 Cordis memo which describes 134 premature Gamma battery depletions. Also attached was another document describing apparent GMP problems concerned with the manufacture of these batteries (copies attached).

Please conduct an investigation at your earliest opportunity in order to obtain the facts surrounding this problem. We have available support in the event it is needed. You may contact either Howard Bassen, HFX-240 or Don Dahms, HFK-450.

At the conclusion of your investigation please send a copy of your report with all exhibits to HFK-116.

276

Bittenbender
John A. Bittenbender

Attachments:
As Stated

PC :74DXY
PAC :78K001
Priority :High
Est. Time :20 Hours
Est. Comp. Date :12/15/83
Contact Officer :John A. Bittenbender
8757 Georgia Avenue
Silver Spring, MD 20910
(8)427-7304

I-476
Mea-KSC

Pls assign appropriate plan
CA 11/7/83

TD 10/4/83

Memorandum

Cordis

CONFIDENTIAL

Date: November 23, 1983

To: Divisional Managers   Site Location

From: Kevin T. Larkin   K.T.L.

Subject: Gamma Situation

The information in this memo supplements that in my communication to the Sales Force regarding the Physician Advisory and is for your eyes only. I'll be brief.

This is a Medical Device Notification that will probably be labeled a recall by the F.D.A. It is intended to explain the nature of the problem and recommendations for monitoring suspect pacers.

Not all suspect pacers will prematurely deplete. There is no way of determining the extent of failures yet to come. Conservatively, all pacers that could conceivably fail are included now so we can avoid expanding our suspect lots later. For your information, the worldwide quantity of pacers by model number in the suspect group is as follows:

333 - 1,306
334 - 6,447
336 - 322
337 - 1,014
340 - 19

Remember, monitoring is the key! In the interests of avoiding a sudden high number of explants and minimizing customer concern about our products quality, we need to convince physicians that what we're dealing with is detectable and pacers capable of reaching their intended longevities should be left in long enough to do so.

We will make it easy to follow pacers through CDI. Sheri can sign up patients simply by having the salesmen indicate which ones on the printouts should be enrolled. As my memo to the Sales Force indicates, under CSP, the patient's third party carrier will be billed only for the allowable charge. For your information, if a physician insists we pick up the monitoring charge, we can. It will be very expensive, so keep it for discretionary use and when instituted, make your salesman feel that you made a significant exception just for him.

You also have some additional flexibility regarding replacements. Remember, in the Sales Force's communication I specified:

1) Cordis will provide 100% of the original purchase price of the pacer removed, toward the cost of the replacement pacer. The mechanics of this will be through a sale and then a 100% credit applied on the original purchase price of the removed unit.

2) P.P.A. is available for all additional charges not covered by the patient's insurance carrier up to $5,000.00.

3) The replacement options mentioned in this memo and the memo to salesmen cover only pacers on the notification. Our standard replacement policy continues to be in force for all other Gamma Pacers.

As we have discussed, the financial interests of the company could be severely damaged without firm control and good judgment here. We can ensure that patients are safely monitored and paced with our products while relying on third party coverage to do what it is designed to do. By first minimizing any drives to explant units unnecessarily and then judiciously using the replacement options, we should maintain control over this situation.

Your newer, less experienced salesmen may need special attention, at least at first. If you have more salesmen in this category than you personally have time to handle, by all means enlist the help of your most mature, seasoned salesmen, particularly those who have been through this before. If any Miami personnel can be of assistance, please contact Tom or me and we will coordinate that assistance.

As we proceed, please forward any suggestions, tips, or observations worthwhile. Stay in touch.

KTL/lb

cc: Dick Spencer
Todd Davenport
Tom Brown
Norm Baker
Stu Finch

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION	DISTRICT ADDRESS 305-855-0900 7200 Lake Ellenor Dr., Suite 120 Orlando, FL 32809
NAME OF INDIVIDUAL TO WHOM REPORT ISSUED TO: Norman R. Weldon, Ph.D.	DATE OF INSPECTION *
	C. F. NUMBER
TITLE OF INDIVIDUAL President	TYPE ESTABLISHMENT INSPECTED Device Manufacturer
FIRM NAME Cordis Corporation	NAME OF FIRM, BRANCH OR UNIT INSPECTED Same
STREET ADDRESS 10555 W. Flagler St.	STREET ADDRESS OF PREMISES INSPECTED Same
CITY AND STATE Miami, FL 33172	CITY AND STATE Same

DURING AN INSPECTION OF YOUR FIRM (I) ~~(WE)~~ OBSERVED:

* The dates of this inspection are as follows: 12/3, 5-8, 12-16, 19, 20, 22/83; 1/17-20, 23-25/84; 2/6-10, 13-17, 21-23, 26/84; 3/7-9, 12/84; 4/2/84

I. THE FOLLOWING OBSERVATIONS RELATE TO THE CURRENT POWER CELL MANUFACTURING OPERATION:

(1) Cordis Standard Practice concerning "Receiving and Inspection of Incoming Material" dated September 20, 1983 (CSP 14-02-02) allows for the "Conditional Release" of components to production prior to the completion of the required inspections. This practice may result in the acceptance of finished devices having one or more marginal components due to economic influences.

(2) The protocol for the qualification of Northeast Electronics Corp., Milford, CT., coined lids with integral cut glass feedthroughs for Gamma cells (482-02-008) states that, as part of the acceptance criteria for the lids, "There shall be no evidence of cracking, breaking, or loosening of parts". However, the qualification report summary states that "Three lids, which had passed hermeticity testing, were found to have cracks in the glass. The exact origin of these cracks could not be determined." The qualification of the Northeast Lid was approved by the Product Engineering Team (PET) despite the lack of conformance with the qualification protocol. No explanation is provided for the qualification approval.

(3) On February 13, 1984, two [redacted] (polypropylene) rolls were noted stored horizontally partially inside a cardboard box with the upper portion of both rolls in direct contact with the stockroom floor in building 7G. A noticeable degree of dirt was present on the exposed surfaces and edges of both rolls. Two other [redacted] rolls without protective covering were noted in the stockroom.

(4) On February 15, 1984, at 10:20 a.m., the cupric sulfide powder Production Log Sheet showed a pre-completion entry for step 7C, (relating to the addition of water after the reaction vessel heater is turned off). The addition of the water was scheduled for 11:30 a.m.; however, the Production Log Sheet misleadingly reflected that the water had already been added.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)* Victor Spaniolá/CSO

FORM FDA 483 (12/78) PREVIOUS EDITION MAY BE USED. INSPECTIONAL OBSERVATIONS PAGE 1 OF 34 PAGES

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION	DISTRICT ADDRESS 305-855-0900 7200 Lake Ellenor Dr., Suite 120 Orlando, FL 32809
NAME OF INDIVIDUAL TO WHOM REPORT ISSUED TO: Norman R. Weldon	DATE OF INSPECTION See first page — C. F. NUMBER
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CITY AND STATE Miami, FL 33172	CITY AND STATE Same

DURING AN INSPECTION OF YOUR FIRM (I) ~~(WE)~~ OBSERVED:

II. THE FOLLOWING ITEMS REFER TO COMPLAINT/RETURNED GOODS INVESTIGATIONS:

● (22) Complaints pertaining to any hazard to safety are not immediately reviewed, evaluated, and investigated nor are they maintained in a separate portion of the complaint file. For example:

(a) Product Service Report (PSR) Number 56498 concerns an individual who "blacked out while driving car" whose pacer was "found to be dead". The suspect pacer (334A-5938) was explanted on October 7, 1983. The PSR was completed by a Cordis salesman on October 12, 1983. The pacer was returned to Cordis on October 18, 1983, and analyzed November 7-10, 1983, with the conclusion that the pacer failed because of early battery depletion (EBD). A health hazard assessment was not initiated until December 3, 1983, when this complaint was brought to the attention of Cordis officials by the Food and Drug Administration.

(b) PSR Number 78621 concerns Pacer 334A-4214 that had a "rate decrease" and also was reported to be a "Runaway at 160-170 ppm." The pacer was explanted on October 18, 1983, and returned to Cordis on November 1, 1983. The pacer was analyzed on November 16, 1983, with the conclusion that the pacer failed due to EBD. A health hazard assessment was not initiated until December 16, 1983, after this complaint was brought to Cordis' attention during this inspection.

(c) PSR number 56152 concerns pacer 334A-6096 that was explanted on August 10, 1983, due to a rate decrease with a complaint that the patient experienced "dizzy spells". The pacer was returned to Cordis and analyzed on September 14, 1983. The pacer had a rate of 61.8 instead of 70.0. The analysis concluded that the pacer failed due to early battery depletion. No additional investigation had been conducted prior to this inspection to determine if the dizzy spells were related to the pacer failure. 4/14/84 VS

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type) Victor Spaniol1/CSO

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION	DISTRICT ADDRESS 305-855-0900 7200 Lake Ellenor Dr., Suite 120 Orlando, FL 32809
NAME OF INDIVIDUAL TO WHOM REPORT ISSUED TO: Norman R. Weldon	DATE OF INSPECTION See first page
	C. F. NUMBER
TITLE OF INDIVIDUAL President	TYPE ESTABLISHMENT INSPECTED (i.e. bakery, cannery) Device Manufacturer
FIRM NAME Cordis Corporation	NAME OF FIRM, BRANCH OR UNIT INSPECTED Same
STREET ADDRESS 10555 W. Flagler St.	STREET ADDRESS OF PREMISES INSPECTED Same
CITY AND STATE Miami, FL 33172	CITY AND STATE Same

DURING AN INSPECTION OF YOUR FIRM (I) ~~(WE)~~ OBSERVED:

(23) (a) Cordis Standard Practice (CSP) Number 14-08-02 dated December 15, 1980, states that "The Cordis employee who first receives an oral or written report about the performance of a Cordis product shall promptly write a Product Service Report (PSR) (see attachment)". The attachment referred to is the Cordis in-house complaint handling form and not the similarly named form normally completed by the explanting physician or an associate. The majority of the approximately 248 complaints reviewed through December 31, 1983, did not include the Cordis in-house PSR.

(b) CSP No. 14-08-02 also states that Product Service "Alerts the Vice President of Product Assurance immediately regarding any report alleging injury, suspected related death, or a health hazard". The Vice President of Product Assurance was not aware of the three complaints specified in Item (1) nor is there any documentation attesting that the Vice President of Product Assurance had been alerted.

• (24) On December 25, 1983, it was brought to the attention of a Cordis Sales Representative that Gamma pacer 334A-2511 had malfunctioned. Surgery was scheduled at the [redacted], FL., on the following day. The Sales Representative visited the hospital on December 26, 1983, and obtained the malfunctioning pacer. However, a PSR was not submitted to Product Service by the Sales Representative and the pacer was not sent to Cordis for evaluation until February 6, 1984. According to attending physicians, the pacer failure resulted in the patient's cardiac arrest.

(25) The PSR form is not designed to elicit specifically any adverse affects that may have been experienced by a patient as a result of a product failure. Consequently, the Product Service Department cannot readily determine if an investigation is warranted to assure that patient safety was not compromised.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*) Victor Spanioli/CSO

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION	DISTRICT ADDRESS 305-855-0900 7200 Lake Ellenor Dr., Suite 100 Orlando, FL 32809	
NAME OF INDIVIDUAL TO WHOM REPORT ISSUED TO: Norman R. Welden	DATE OF INSPECTION See first page	C. F. NUMBER
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CITY AND STATE Miami, FL 33172	CITY AND STATE Same	

DURING AN INSPECTION OF YOUR FIRM (I) ~~WE~~ OBSERVED:

(26) As of February 1, 1984, there were a total of 270 expired patients that had Gamma pacers subject to the December 5, 1983, Gamma notification. Prior to this inspection, no effort had been made to determine if the recognized pacer early battery depletion failure mechanism could have resulted in a patient death that may have been mistakenly attributed to non-pacer related causes because a physician had no reason to suspect early pacer failure.

(27) Prior to this inspection, a health hazard analysis was not done for the following Product Service Reports:

Product Service Report No.	Date Pacer Received	Model # and Serial # of Pacer	Patient Complaint
56499	10/18/83	334A-2348	"symptoms"
75559	1/29/82	333B7-320	"dizzy spells"
56152	8/31/83	334A-6096	"dizzy spells"
77222	2/16/83	334A-3212	"fatigue"
77435	4/14/83	337A-246	"unresponsive intermittently"

(28) Cordis returned goods procedure requires that returned implantable devices be held in the returned goods area until the initial paperwork is processed by the Product Service Department. As individual receiving tickets are completed for each returned device, there is no system in effect that can readily identify the status of each device, i.e., device in returned goods area awaiting release to failure analysis, device sent to failure analysis, etc.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Victor	EMPLOYEE(S) NAME AND TITLE (Print or Type) Victor Spanioli/CSO

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION	305-855-0900 7200 Lake Ellenor Dr., Suite 120 Orlando, FL 32809
NAME OF INDIVIDUAL TO WHOM REPORT ISSUED TO: Norman R. Weldon	DATE OF INSPECTION 12/3/83 - 4/2/84 | C. F. NUMBER
TITLE OF INDIVIDUAL President	TYPE ESTABLISHMENT INSPECTED Device Manufacturer
FIRM NAME Cordis Corporation	NAME OF FIRM, BRANCH OR UNIT INSPECTED Same
STREET ADDRESS 10555 W. Flagler St.	STREET ADDRESS OF PREMISES INSPECTED Same
CITY AND STATE Miami, FL 33172	CITY AND STATE Same

DURING AN INSPECTION OF YOUR FIRM (I) ~~(WE)~~ OBSERVED:

(44) In a memorandum dated September 15, 1980, from Mr. Solomon and from Mr. DeHaan re: "Trip Report on Visit to [redacted], one of the conclusions drawn in this report is that, "Of the two aspects of the corrosion reaction (1) vertical degradation leading to potential stresses and mechanical failure of the feedthru, and (2) formation of conductive bridges between terminals, it appears that the latter is of more concern in the Cordis cell system. Evaluation of this is essential for prediction of future integrity of all feedthrus."

(45) Based on the above reports and other Cordis reports demonstrating feedthrough corrosion and high feedthrough conductivity, polypropylene was selected to protect the glass insulator from lithium attack beginning with Gamma cell lot number 4180 (October, 1980).

(46) In spite of the data presented above and other information available to Cordis which documented the internal discharge mechanism of Gamma cells which results in early battery depletion, approximately 6,327 pacers which incorporated cells with unprotected feedthroughs were distributed from November, 1980 through August, 1983 after the Gamma cell design was improved to minimize or eliminate feedthrough corrosion and loss of resistance.

(47) The use of polypropylene to protect the feedthrough insulator is questionable and may not in all instances afford sufficient protection of the feedthrough insulator to prevent corrosion and feedthrough loss of resistance. Chemical and Physical Quality Assurance report # 23-03536 dated December 10, 1982 states that "In a Fusite control complete protection was not achieved with mild corrosion occurring under the polypropylene protector. This variability is consistent with previous studies on polypropylene protectors and accounted for the recommendation to use polyimide as a mask." Cordis continues to use polypropylene protected Fusite feedthroughs in the Mini-Gamma cells.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Victor Spanioli	EMPLOYEE(S) NAME AND TITLE (Print or Type) Victor Spanioli/CSO

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DURING AN INSPECTION OF YOUR FIRM (I) ~~(WE)~~ OBSERVED:

IX. GENERAL OBSERVATIONS

(109) A two-page memorandum dated August 19, 1983, from J. Pagones, Vice President, Corporate Product Assurance, to N. Weldon, H. Hershenson, F. Fischer, R. Smolowitz, B. Nickerson, K. Jones, S. Saulson, R. Spencer, D. Colbert, J. Schwoebel, D. Bump, R. Gjertson, D. Hart, C. Jimenez, H. Tataria, and P. Watson, titled "Gamma Cells and Gamma Pacers - Task Force" which identified eight factors that the Task Force should consider or investigate relating to the Gamma pacer early battery depletion situation, was revised, on or about December 1, 1983. The revised memorandum (one page); however, has the August 19, 1983, date and deletes the aforementioned eight factors. The revised memorandum has the same distribution as the original; however, Mr. Watson, denied receiving a copy of this memorandum. The other individuals were not asked if they had received the one-page memorandum. FDA requested the Task Force assignment memorandum on December 3, 1983, and the one page revised memorandum was provided by Mr. Pagones on December 7, 1983.

(110) Cordis Gamma pacers notification letter dated December 5, 1983, stated that early battery depletions had occurred in 2.1% of the pacers subject to the notification. However, Cordis records show that as of November 30, 1983, the early battery depletion rate was actuallyt 2.5%.

(111) Examination of the notification/recall distribution accountability data revealed that all pacers incorporating suspect cells had not been identified. Further review of records by Cordis uncovered an additional 60 pacers that included suspect cells. Two of these pacers were Custom or "Engineering Order" pacers - Model number EO 306.

(112) The notification cover letter dated December 14, 1983, states that, "Information received from other physicians indicate that you are following the additional patient(s) on attached list". This letter is misleading in that the "additional patient(s)" were determined due to FDA evaluation of accountability data and not from "Information received from other physicians".

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)* Victor Spanioli/CSO

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION	305-855-0900 7200 Lake Ellenor Dr., Suite 120 Orlando, FL 32809
NAME OF INDIVIDUAL TO WHOM REPORT ISSUED TO: Norman R. Weldon	DATE OF INSPECTION See first page
TITLE OF INDIVIDUAL President	TYPE ESTABLISHMENT INSPECTED Device Manufacturer
FIRM NAME Cordis Corporation	NAME OF FIRM, BRANCH OR UNIT INSPECTED Same
STREET ADDRESS 10555 W. Flagler St.	STREET ADDRESS OF PREMISES INSPECTED Same
CITY AND STATE Miami, FL 33172	CITY AND STATE Same

DURING AN INSPECTION OF YOUR FIRM (I) ~~(WE)~~ OBSERVED: 4/10/84 VS

(113) Device history record (~~[illegible]~~ travel card) for pacer 334A/1708 shows that cells from lot 1480 were used on May 2, 1980, and were replaced on June 4, 1980 by cells from lot 1880. However, the computer printout dated December 5, 1983, titled "All Gamma Pacers with Batteries prior to lot 4280" shows that pacer 334A/1708 contains cells from lot 1480.

(114) The investigation of the early battery depletion failure mechanism concerning Gamma Series pacers as it relates to processing deviations was treated as an internal audit rather than a complaint investigation (as of March 19, 1984, 574 confirmed and suspected complaints had been received) or as a device failure investigation. All official copies of the failure investigation report were destroyed. After the firm had been advised that the failure to provide a report of their Gamma cell investigation was considered to be an inspectional refusal, a copy of the report was provided. This copy was provided even though Cordis had advised that all copies had been destroyed.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Victor Spanioli	EMPLOYEE(S) NAME AND TITLE (Print or Type) Victor Spanioli/CSO

14 IH-RY ay

Supervisory Investigator, HFR-A575
Miami Resident Post

December 9, 1983

Investigator, HFR-A575
Miami Resident Post

Manufacturer: Cordis Corporation
10555 W. Flagler St.
Miami, FL 33172

Recommendation for
Recall Information
Concerning Gamma Series
Pacers, Models 333B7, 334A,
336A, 336B, 337A, and 340A

1. PRODUCT: The following are the Gamma Series pacemakers affected by the Cordis Corporation: "Urgent Medical Device Notification" letter dated December 5, 1983.

(1) Stanicor γ(Gamma), Model 333B7, Lithium-Powered, VVI (R-Wave Inhibited), Unipolar, Nonprogrammable Cardiac Pacer (labeling is submitted as Exhibits #10 and #11);

(2) Omni-Stanicor γ(Gamma), Model 334A, Lithium-Powered, VVI (R-Wave Inhibited), Unipolar, Programmable Cardiac Pacer (see Exhibits #12, #13, and #14);

(3) Multicor γ(Gamma), Model 336A Lithium-Powered, VVI/VVT/VOO, Bipolar, Multiprogrammable Cardiac Pacer (see Exhibits #15, #16, and #19);

(4) Multicor γ(Gamma), Model 336B Lithium-Powdered, VVI/VVT/VOO, Bipolar, Multiprogrammable Cardiac Pacer (see Exhibits #15, #16, and #19);

(5) Multicor γ(Gamma), Model 337A, Lithium-Powered, VVI/VVT/VOO, Unipolar, Multiprogrammable Cardiac Pacer (see Exhibits #15 and #19);

(6) Multicor γ(Gamma), Model 340A, VVI/VVT/VOO, Multiprogrammable Cardiac Pacer (see Exhibits #17, #18, and #19).

Common labeling for the above cited pacers is submitted as Exhibits #20, #21, and #22 (for models 336A, 336B, and 337A).

~~Model~~ 341?

2. SCOPE: All Gamma pacemakers containing lithium batteries manufactured from November 1979 through October 1980 are affected by this recall. A total of 10,376 pacemakers were manufactured utilizing such lithium batteries. Serial numbers of affected pacers have been identified and will be submitted at a later date. Investigation has determined that there are other pacemakers containing the suspect lithium batteries that may be

Area #1

affected. These additional pacemakers are currently being identified by Cordis.

3. RECALLING FIRM/MANUFACTURER: The recalling firm and manufacturer is Cordis Corporation, 10555 West Flagler St., Miami, FL. 33172. The firm's European subsidiary Cordis Europa N.V., P.O. Box 39, Roden, The Netherlands, received 2,182 suspect lithium batteries for usage with those pacers manufactured in their plant. Cordis Europa has been sent the notification letter and will handle their portion of the recall involving pacers containing the suspect cells as well as the pacers distributed by Cordis Corporation.

Cordis Corporation is responsible for the defective pacemakers.

4. REASON FOR RECALL: The Miami Office of the Food and Drug Administration was contacted by Joseph J. Schwoebel, Manager, Regulatory Affairs, on late Friday afternoon, December 2, 1983, to advise of the firm's recall of the aforementioned pacemakers. Exhibit #1 is the firm's "Urgent Medical Device Notification" letter dated December 5, 1983, that was mailed to all affected monitoring and implanting physicians on December 2, 1983. This notification summarizes the reason for the recall.

The firm has determined that certain Cordis Gamma Series pacers may not provide their expected length of service because of early battery depletion. Cordis' investigation revealed that these early depletions were caused by loss of electrical capacity through self-discharge. Worldwide early battery depletions have occurred in approximately 2.1% of the implanted Gamma Series pacers made with cells manufactured in October, 1980 or earlier; however, certain battery cell lots have depletion rates as high as 20%.

Normally, impending battery depletions in Gamma Series pacers are indicated by a marked decrease in the fixed rate. This lower rate then persists for about six months, providing ample time to schedule pacer replacement before the battery is exhausted. The units experiencing early battery depletions are also characterized by a rate decrease. However, in these cases the pacer operates for only about one to two months at the lower rate before battery exhaustion.

Cordis recommends monthly monitoring after 24 months of implant of all patients with Gamma Series pacers having batteries manufactured before November 1980. Any unit with a fixed rate decrease of 3% or more should be replaced promptly.

Exhibit #2 is the Cordis Product Update #19 dated November 1983 titled "Achieved Reliability of Gamma Series Pacers", which was mailed during the week of December 5, 1983. This update also discusses the premature battery depletions associated with Gamma Series pacers. This Product Update will be mailed to approximately 15,000 physicians that have registered Cordis pacemakers.

Cordis has received a total of 261 complaints concerning no output or low output failures involving Gamma Series Pacers. Ten of these were received in 1981, 13 were received in 1982, and the remaining 238 were received in 1983 through November 23, 1983. Fifty-four of these 238 failures have yet to be confirmed; however, Cordis believes that most, if not all, will exhibit the same failure mode. Exhibit #28 summarizes the 1983 complaints.

Please note that the increased number of explants raises the worldwide percentage rate of failures to 2.4% as compared to the 2.1% mentioned in the December 5, 1983, notification which only included explants through October 31, 1983.

Exhibit #3 is the only complaint involving a Gamma pacer premature battery depletion failure that resulted in a patient's loss of consciousness. The patient received a new pacemaker without any adverse consequence. Exhibit #8.5 is another Gamma premature battery depletion report which reports that the patient was experiencing dizzy spells. All of the confirmed premature battery depletion complaints have been reviewed and no others were found that reported any adverse effects. Cordis officials have stated that they know of no injuries, deaths, or any other hazards.

Exhibits #5, #7, and #9 are typical of the other premature battery depletion complaints evaluated by Cordis.

5. VOLUME OF PRODUCT IN COMMERCE: Exhibit #3 is a breakdown of the Gamma pacemakers affected by this situation. A total of 10,878 pacers were manufactured. These pacers are broken down as shown in Exhibit #3, page 1, which accounts for 10,860. The remaining 13 affected pacers are listed in Exhibit #29 (these are all Model 380A). Exhibit #3, page 2 describes a total of 7577 pacemakers that have been registered by country of registration. Cordis records show that a total of 2,818 different physicians have registered these pacers worldwide with 2,335 United States physicians registering these patients. Exhibit #3, page 3 provides a breakdown by model number of the total pacemakers affected by this recall.

Accountability of the 10,878 pacers incorporating suspect batteries is as follows:

a) Registered Pacers: 7,577 (Exhibit #37).
b) 380A Registered Pacers: 13 (Exhibit #29).
c) Explants: 728.
d) In-house (life test, scrapped, etc.): 465.
e) Unregistered direct sales to U.S. Hospitals: 268 (Exhibit #35).
f) Cordis Sales Personnel: 14.
g) Demo units: 11.

h) Cordis Europa, Roden, The Netherlands: 1551 (Exhibit #35).
i) Weich, Int. Co., Ltd, Hong Kong: 45 (Exhibit #31).
j) Equilab, Venezuela: 1 (Exhibit #34).
k) Brent, Ltd., Toronto, Canada: 13 (Exhibit #33).
l) Marcapassos Do Brazil Ltd.: 15 (Exhibit #32).
m) Instrumed, Mexico: 2 (Exhibit #30).

Addresses for the above international distributors are included in the Exhibits.

6. DISTRIBUTION PATTERN: As shown in Exhibit #3, distribution is worldwide with a number of foreign countries also affected by this recall. Exhibit #37 shows all domestic and foreign registered pacemakers and the state or country of patient location.

The addresses for the Cordis foreign distributors are provided in Exhibit #4 and countries involved include The Netherlands, Hong Kong, Venezuela, Canada, Brazil and Mexico. The Cordis Europa plant distributes pacemakers throughout Europe. The Hong Kong distributor also distributes to Japan and Thailand. There are no government contract sales involved. However vendors sell directly to Veterans Hospitals (see Exhibit #36).

The suspect pacers were distributed primarily from December 1979 through 1981. A small number may also have been distributed from 1982 through early 1983.

7. THE FIRM'S RECALL STRATEGY: As noted above, the firm has sent a Device Notification letter dated December 5, 1983. Each physician notified received an attached list which specified the registered pacers unique to him. A postage paid reply card was also sent along with the notification letter. A specimen of this card is submitted as Exhibit #1, page 2. The notification information was mailed in a 9-1/2 inch by 12-1/2 inch envelope marked "URGENT Medical Device Notification Open Immediately" in the bottom left-hand corner and "FIRST (in red type) CLASS" on the right bottom side of the envelope.

Exhibit #23 is a letter dated December 5, 1983, that will be hand delivered by Cordis salesmen to U.S. Hospitals appearing on Exhibit #36. Delivery is scheduled to take place beginning the week of December 12, 1983. Exhibit #24 is a memorandum to Cordis salesmen dated 12/5/83 which describes how the salesmen are to handle the notification at these hospitals. All distributors have received the notification information as verified by documents submitted as Exhibits #25 and #26.

8. FIRM OFFICIAL: The firm official for this recall is James Fortino, Product Service Dept., 1-800-327-2490, Cordis Corporation, Miami, Florida.

9. CORRECTIVE MEASURES: Exhibit #5 is a memorandum titled Gamma Cells &

Pacers - Lithium Cell Task Force Final Report, prepared by Cordis Corporation that describes the corrective actions that have been taken to prevent a similar reoccurrence in the future. An inspection of the firm's Lithium battery operation is in progress.

Cordis issued a News Release dated December 5, 1983, concerning this matter (Exhibit #27).

Victor Spanioli

recd: 12/5/83
draft: 12/5/83
final: 12/9/83
/mal

Cordis Corporation
P.O. Box 025700
Miami, FL 33102-5700 U.S.A.
Telephone 305-551-2000
Telex 6811112

Cardiovascular Instrumentation

cordis.

December 5, 1983

RE: CORDIS CORPORATION
[illegible]/3/83 VS
EXHIBIT 1 PAGE 1 OF 3

URGENT MEDICAL DEVICE NOTIFICATION

GAMMA SERIES PACERS

Models 333B7, 334A, 336A/B, 337A, 340A

Dear Doctor:

This notification is provided to assist you in the management of patients with certain Cordis Gamma Series pacers which may not provide their expected length of service because of early battery depletion. Gamma Series pacers have had an excellent record of reliability until recently, when a number of early battery depletions, commencing after 24 months of implant, were reported.

Investigation revealed that these early depletions were caused by loss of electrical capacity through self-discharge. Worldwide, early battery depletions have occurred in 2.1% of the implanted Gamma Series pacers made with cells manufactured in October, 1980, or earlier. Except for a few random units, such early depletions have not occurred in cells manufactured after October, 1980, when an insulator was added to protect the cell feedthrough from electrolyte attack which could lead to self-discharge. No early depletions have been reported in units of Model 402A/B, all of which were made with cells manufactured after October, 1980.

Normally, impending battery depletions in Gamma Series pacers are indicated by a marked decrease in the fixed rate. This lower rate then persists for about six months, providing ample time to schedule pacer replacement before the battery is exhausted. The units experiencing early battery depletions are also characterized by a rate decrease. However, in these cases the pacer operates for only about one to two months at the lower rate before battery exhaustion.

On the basis of the above information, Cordis recommends monthly monitoring after 24 months of implant of all patients on the attached list, which includes all patients with Gamma Series pacers having batteries manufactured before November, 1980, who are in your care according to Cordis records. If you have any questions about a Gamma pacer not on the list, please call the number given below. Any unit with a fixed rate decrease of 3% or more should be replaced promptly.

If you find it necessary to replace one of the units on the enclosed list due to early battery depletion, Cordis will provide full credit for the original purchase price toward the cost of any Cordis replacement pacer.

Cordis sincerely regrets any inconvenience that this notification may cause you and your patients. If you have any questions regarding this notification, please call James Fortino in our Product Service Department at 1-800-327-2490 or contact your local Cordis representative.

IMPORTANT:

Please acknowledge receipt of this notification and the enclosed patient list by signing and returning the enclosed prepaid postage card. The returned card will help us to assure that all affected physicians have received this information.

cordis®

Product Update
Number 10 November 1983

[illegible] CORDIS CORPORATION
[illegible] 3/83 VS
EXHIBIT 2 PAGE 1 OF 4

Achieved Reliability of Gamma Series Pacers

EX: CORDIS CORPORATION
12/3/83, VS
EXHIBIT 2 PAGE 2 OF 4

This update presents the achieved reliability data for all models in the Gamma series for use by monitoring physicians in the management of patients with these pacers.

The Cordis Gamma series of lithium-powered pacers, introduced in 1979, has demonstrated achieved reliability that thus far meets or exceeds the predicted reliability, with the exception of Model 334A which is .012 below its predicted reliability after 44 months.

When Gamma series pacers were introduced, the labeling included a prediction of reliability based on the performance of the earlier Lambda series pacers. The following table and figures compare the achieved reliability obtained from data in the Cordis pacer registry as of October 31, 1983, to those reliability predictions, based on the actual length of service for each model.

Comparison of Predicted and Achieved Reliability for Gamma Series Pacers*

Model	Average Malfunction Rate %/Month	Predicted Reliability†	Achieved Reliability‡	at Month
308A	0.017	0.982	0.997	25
333B7	0.028	0.970	0.983	40
334A	0.041	0.967	0.955	44
336A,B	0.040	0.973	0.990	36
337A	0.015	0.972	0.981	38
340A	0.048	0.974	0.983	29
402A,B	0.067	0.998	0.998	9

*For implants worldwide.

†As published in the *Instructions for Use*, adjusted for time.

‡Calculated using the cumulative survival method.

Predicted vs Achieved Reliability
Gamma Series Pacers

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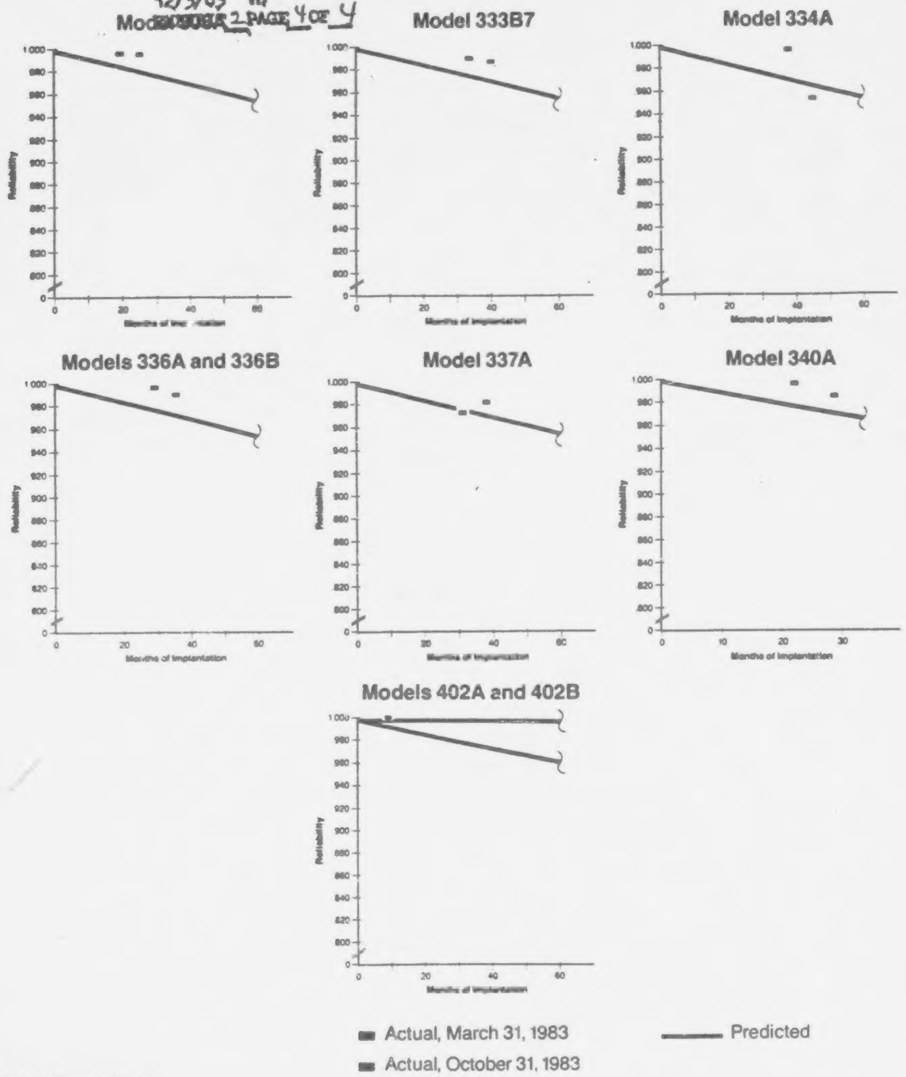
[illegible] 2 PAGE 4 OF 4


Mod[illegible]

Model 333B7

Model 334A

Models 336A and 336B

Model 337A

Model 340A

Models 402A and 402B

Cordis Corporation
Post Office Box 025700
Miami, Florida 33102-5700, U.S.A.
Telephone 305-551-2000

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149-9776

RE: CORDIS CORPORATION
12/3/83 VS
EXHIBIT 2 PAGE 3 OF 4

The reliability predictions for Gamma series pacers were based on the expectation that most malfunctions would be caused by electronic circuit failures which usually occur suddenly and are normally manifested as changes in rate, loss of sensing or loss of capture. Most malfunctions, in fact, have not been caused by electronic circuit failure but by early battery depletion which can be detected by rate decrease.

Investigation revealed that these early depletions were caused by loss of electrical capacity through self-discharge. Worldwide, early battery depletions have occurred, commencing after 24 months of implant, in 2.1% of the implanted Gamma Series pacers made with cells manufactured in October, 1980, or earlier. Except for a few random units, such early depletions have not occurred in cells manufactured after October, 1980, when an insulator was added to protect the cell feedthrough from electrolyte attack which could lead to self-discharge. No early depletions have been reported in units of Model 402A/B, all of which were made with cells manufactured after October, 1980.

Normally, impending battery depletions in Gamma Series pacers are indicated by a marked decrease in the fixed rate. This lower rate then persists for about six months, providing ample time to schedule pacer replacement before the battery is exhausted. The units experiencing early battery depletions are also characterized by a rate decrease. However, in these cases the pacer operates for only about *one to two months* at the lower rate before battery exhaustion. Although all models of the Gamma Series have met their predicted reliability, except for Model 334A, which is close, Cordis has sent a notification letter to all affected physicians.

The Notification recommends monthly monitoring after 24 months of implant of all patients with Gamma Series pacers having batteries manufactured before November, 1980 and prompt replacement of any unit with a fixed rate decrease of 3% or more.

The information in this Product Update will be followed carefully and reviewed in the next Product Update on Gamma Series pacers.

Monitoring Physician:

To:
Cordis Corporation
Product Service Department

I acknowledge receipt of the **Urgent Medical Device Notification** on Cordis Gamma Series pacers dated December 5, 1983 and have reviewed the enclosed list of my patients having these pacers.

☐ The list is accurate

☐ The list should be corrected as noted

Signed ______________________________

Date ______________________________

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12/3/83 VS
EXHIBIT 1 PAGE 2 OF 3 (Back)

cordis.
Cordis Corporation
Post Office Box 025700
Miami, Florida 33102-5700

GAMMA NOTIFICATION ACCOUNTABILITY

11/30/83
Corrected

10878

EX: CORDIS CORPORATION
12/3/83 VR
EXHIBIT 3 PAGE 1 OF 3

Total Manufactured	10860		
Registered Implants (-Roden)	8305		
Explants (-Roden)	728		
Net Registered Implants (-Roden)	7577		
Remaining Pacers (Detailed below)	2555		
- In House		495	
- Unregistered Direct Sales to U.S. Hospitals		268	
- Cordis Sales Personnel		14	
- Demo Units		11	
- Direct Sales to Foreign Distributers		1767	
Cordis Europa			1691
Neich			45
Equilab, Venezuela			1
Brent, Canada			13
Brazil			15
Instrumed, Mexico			2

→ 218 Unregistered direct sales from ~~[illegible]~~ Cordis
5
50 salesman-sales

RE: CORDIS CORPORAT
12/3/83 VS
EXHIBIT 3 PAGE 2 OF 3

```
     GAMMA PACER IMPLANT STATISTICS
DATE: 12/01/83    TIME OF DAY: 13.26.25

NUMBER OF JAPANESE IMPLANTS          506
NUMBER OF UNITED STATES IMPLANTS    6552
NUMBER OF CANADIAN IMPLANTS          435
NUMBER OF OTHER IMPLANTS              71
NUMBER OF EXPLANTS                    13*
                                    ----
              TOTAL IMPLANTS:       7577
                                    ====

NUMBER OF UNIQUE PHYSICIANS:  2814

*THE NUMBER OF EXPLANTS FOUND AS OF NOVEMBER 29, 1983
 AFTER THE ORIGINAL EXTRACT TAKEN NOVEMBER 17, 1983
```

→ OTHER FOREIGN COUNTRIES

2435 - DOMESTIC ONLY PHYSICIANS

RE: CORDIS CORPORATION
12/3/83 VE
EXHIBIT 3 PAGE 3 OF 3

TOTALS FOR MODEL 333B7	TOTAL UNITS =	1,710
TOTALS FOR MODEL 334A	TOTAL UNITS =	7,637
TOTALS FOR MODEL 336A	TOTAL UNITS =	415
TOTALS FOR MODEL 336B	TOTAL UNITS =	1
TOTALS FOR MODEL 337A	TOTAL UNITS =	1,097
TOTALS FOR MODEL ALL	TOTAL UNITS =	10,860
Totals For Model 340A		18
		10,878

EX: CORDIS CORPORATION
12/3/83 VS
EXHIBIT 4 PAGE 1 OF 1

① Cordis Europa N.V.
P.O. Box 39
Roden
The Netherlands

② Neich, Int. Co., LTD.
Rm 1903-5 Dominion Ctr.
37-59 Queens Road East
Hong Kong

③ Equilab C.A.
Edificio Titania 4o piso
Entrada "c"
Plaza La Estrella
San Bernardino
Caracas, Venezuela

Mailing Address
Apartado 60457
Caraces 1060, Vz.

④ Brent, Ltd.
265 Bartley Dr.
Toronto, Ont. M4A 2N7

⑤ Marcapassos Do Brazil, Ltd.

Rio de Janiero, Ltd.

⑥ Instrumed
Calzada Generalisimo Norte No. 559
Sector Hidalgo
Guadalajara, Jalisco, Mexico

cordis.

Memorandum

THIS IS A RETRIEVABLE
DOCUMENT (19)
DO NOT REPRODUCE

CORDIS
CONFIDENTIAL

Date November 30, 1983
To J. Pagones
From O. Jimenez
Subject Gamma Cells and Pacers - Lithium Cell Task Force Final Report

I. Introduction

The objective of the Task Force appointed by you on August 19, 1983, was to (1) define the extent of early battery depletion, (2) determine the underlying cause of early depletion and (3) recommend any necessary corrective actions. This report documents the Task Force's findings.

II. Task Force Findings

A. Extent of EBD

Gamma pacer EBD returns are occurring predominantly in cell lots manufactured prior to cell lot 4280, which were

CORDIS CORPORATION
12/2/83 VS
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manufactured before the 42nd week of 1980. Table I describes implant and explant data on Gamma series pacers made from these cell lots.

B. Probable cause of EBD

The primary cause of EBD is believed to be related to interaction between the cell electrolyte and the glass insulator in the cell feedthrough. The reduction in useful battery capacity appears to be due to self discharge, caused by conduction through a thin layer of lithium metal or a lithium complex that is deposited from the electrolyte onto the glass insulator of the feedthrough, then disappears through further reaction with the barium, potassium, or silicon oxides in the glass insulator, forming non-conductive lithium oxide. Therefore, the lithium metal deposit forms a temporary conductive path which results in self discharge until the lithium is consumed and converted to nonconductive Li_2O by the reaction with BaO, SiO_2 or K_2O. The proposed mechanism is:

(1) $Li^+ + e^- \text{ —— } Li^0$ or Li complex (Conductive)

$$\left.\begin{array}{ll} (2) & 4\,Li^0 + SiO_2 \text{ —— } 2\,Li_2O + Si^0 \\ \text{or} & 2\,Li^0 + K_2O \text{ —— } Li_2O + 2K^0 \\ \text{or} & 2\,Li^0 + BaO \text{ —— } Li_2O + Ba^0 \end{array}\right\} \text{(Non-Conductive)}$$

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[illegible] VS
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Accelerated laboratory experiments have confirmed that the insulation resistance of the Gamma cell feedthrough can decrease from $10^9 \Omega$ to a range of 300 to 2,300 Ω in cells stored at 80°C for approximately 6 weeks.

C. Corrective Action

In June, 1980, feedthrough glass erosion was observed in Gamma cells. Further studies were initiated as a result of a presentation and a publication by Samuel Levy of Sandia Laboratories(1), which described erosion of the glass feedthrough insulator in a lithium-sulfur dioxide cell.

Initial Cordis investigations determined that a similar erosion of the feedthrough glass insulators occurs in Gamma cells. Feedthroughs removed from Gamma cells evolved hydrogen when immersed in water, indicating the presence of lithium metal or oxide. However, the insulation resistance of the insulators was not reduced from an acceptable value of about $10^9 \Omega$. Analysis of seven 0.5 - 1-year old Gamma cells revealed that 1 - 2 % of the glass had been removed by erosion. Again, the insulators retained acceptable insulation resistance. Further, residual lithium analyses on these units confirmed adequate cell capacity with no indication of self-discharge. Studies on four other 1-year old Gamma cells showed feedthrough glass

RE: CORDIS CORPORATION
12/3/83 VE
EXHIBIT 5 PAGE 4 OF 10

insulator erosion but, again, the feedthrough resistance remained acceptably high and residual lithium analyses showed no indication of self discharge.

Microprobe analysis revealed no evidence of any difference in current leakage between cell feedthroughs from EBD cells and normally functioning cells.

Despite the lack of any evidence that the corrosion of the feedthrough adversely affected feedthrough insulator resistance, Cordis added a polypropylene shield to protect the glass feedthrough insulator from erosion by electrolyte. This feedthrough protection was implemented in Gamma cell lot 4280 after verifying the effectiveness of the polypropylene shield. The polypropylene shield was replaced in March, 1982, by coating the feedthrough insulator with a polyimide resin which provides improved protection.

High temperature (80 - 90°C) studies have confirmed that self-discharge occurs in cells with unprotected feedthroughs and either the polypropylene shield or the polyimide coat is effective in preventing self discharge. Arrhenius plots of time to depletion at several

RE: CORDIS CORPORATION
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temperatures result in a prediction of EBD at 34.6 months at 37°C for cells without protected feedthroughs.

Gamma cells with unprotected feedthroughs from pacers explanted for EBD were analyzed after as long as 42 months of implant. Usually, one cell in each pacer was depleted and the other was not. The viable cell exhibited adequate residual lithium to provide the expected cell capacity with no evidence of self discharge although feedthrough erosion was present. It appears that some feedthroughs are more susceptible to lithium deposition than others, probably because of variations in the composition of the insulator glass.

D. Effect of EBD on End of Life (EOL) Indicator

EBD cells exhibit a correspondingly shorter pacer service life after the initial rate reduction that indicates impending battery depletion. In-vitro studies on production life test pacers show that EBD pacers exhibit an EOL plateau duration of 1 - 2 months. Table 2 describes the EOL characteristics of 12 Gamma pacers that exhibited EBD during in-vitro testing.

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E. Conclusions

The Task Force concludes that cells manufactured without feedthrough protection are susceptible to self discharge caused by lithium deposition on the glass feedthrough insulator. Cell lots produced after lot 4180, when the addition of a polypropylene shield was implemented, have been reliable and are expected to provide their projected useful life.

(1) Bunker, B., et al, Jour. Electrochem. Soc., Oct., 1980 Presented at Power Sources Symposium, Albuquerque, N.M., Sept. 1980 by S. Levy)

OJ:mda

Attach.

cc: F. Fischer
H. Hershenson
C. McDowell
B. Nickerson

RE: CORDIS CORPORATION
12/3/83 VS
EXHIBIT 5 PAGE 7 OF 10

S. Saulson

J. Schwoebel

R. Smolowitz

R. Spencer

E. Tataria

J. Thalen

P. Watson

N. Weldon

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12/3/83 JS
EXHIBIT 5 PAGE 8 of 10

TABLE 1

GAMMA IMPLANTS BY DATE CODE FROM LOT L1579 THRU 4180 (INCLUDING RODEN)

Nov. [illegible]

Lot Number	333B7	334A	336A,B	337A	Total
L1579		4			4
L2079		14(1)			14(1)
L2179		8			8
M0279		12			12
M0479		9			9
M0679		30			30
M1179		5			5
M1379		16			16
M1979		15			15
M2079		40			40
A0380		13			13
A0480		11			11
A0780		22			22
A0880		14			14
A0980		21			21
A1080		14(1)			14(1)
A1180	14	4			18
A1480	12				12
A1580	13	2			15
A1680		11			11
A1780		27(1)			27(1)
A2180		16(1)			16(1)
A2380	14	2			16
A2480		24			24
A2780		1			1
A2880	20	13			33
A2980		26			26
A3080		30			30
A3180		20			20
B0680	12	6			18
B0780		24			24
B1180		25			25
B1280		21			21
B1880		25(1)			25(1)
B1980	8	15			23
B2280		1			1
B2580		23			23
B2680		30			30
B2780		29			29
B2880		42			42

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EXHIBIT 5 PAGE 7 OF 10

replaced 7 out of 18

TABLE 1 (Cont.)

Lot Number	333B7	334A	336A,B	337A	342A	Total
1080	43	176(2)				219(2)
1180	6	118				124
1280	33	191(1)				224(1)
1380	60(1)	105(1)		1		166(2)
1480		17				17
1580	19(2)	95(2)	10	1		125(4)
1680	7	165				172
1780	23	24	1			48
1880		79(4)				79(4)
1980	9	10		2		21
2080		1				1
2180	41(3)	39(1)	10	34(2)		124(6)
2280		156(8)	4	7		167(8)
2380	1	86(10)		14(3)		101(13)
2480	51(4)	178(29)		13(3)		242(36)
2580	13(1)	247(4)	3	60(2)		323(7)
2680	19(1)	235(38)	13	22(5)		289(44)
2780	69(2)	51(3)	9(2)	6(1)		135(8)
2880	40(4)	135(5)	1	11		187(9)
2980		225(3)	18	78(2)		321(5)
3080	70	161(2)		30(1)		261(3)
3180	7	260(3)		2		269(3)
3280		171(5)	1	3		175(5)
3380	71(1)	89		73		233(1)
3480	188(1)	319	5	29		541(1)
3580	17	432(4)	47	66		562(4)
3680	203(2)	291(7)	7(1)	41		542(10)
3780	5	622(10)	23	41		691(10)
3880	132	369(2)	49	98(1)		648(3)
3980	98	426	71(1)	118(1)		713(2)
4080	34	523	18	197(2)		772(2)
4180	47	451(1)	32	67		597(1)
TOTAL	1399(22)	7112(157)	322(4)	1014(23)		9847(206)

NOTE: Numbers in parenthesis denotes the number of failures in specific cell lot, received at Cordis as of October 31, 1983.

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12/3/83 VE
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TABLE 2

GAMMA PACER PLATEAUS FOR PRODUCTION LIFE TEST EARLY BATTERY DEPLETIONS MEASURED DURING ROUTINE BIMONTHLY TESTS

Model/Serial	E.O.L. Plateau Value (p.p.m.)
334A 5920	59.0
334A 0045	64.4
334A 1611	00.0
334A 1805	63.4
334A 1987	66.0
334A 2089	64.2
334A 2454	65.0
334A 3003	65.8
334A 3165	65.0
334A 4743	64.5
334A 0259	63.2
334A 1068	63.5

" 3rd Anonymous
Complaint
Postmarked 2/28/84
Same typewriter as 2/29/84 ltr."

Mr. Donald Dahms
Office of Medical Devices
Food and Drug Administrati
HFK-20
8757 Georgia Avenue
Silver Spring, Maryland

Mr. Dahms,

I am an employee of the Cordis Corporation. While several of their products have problems one in particular is so dangerous I must speak out in order to save lives. Our new Orthocor antytachycardia pacer is plagued with problems. Several dogs have died with the unit implanted. Hardware and software proble abound. It is very susceptible to false triggering by EMI which will result in patient death. Corporate officials want this on the market at all cost. They are aware of the flaws and the very real possibility of patient death and have ignored them. They have altered test data and changed reports to indicate the pacer works. It's not safe! Please, please stop this device, it is a killer.

A.

[illegible] CORDIS CORPORATION
3/15/84 [illegible]
EXHIBIT A PAGE 1 OF 1

Package Postmarked
Feb. 29, 1984.
Opened by Rahmoeller
on March 12, 1984

Mr. Glen Rahmoeller
Food and Drug Administration
Office of Medical Devices
HFK-450
8757 Georgia Avenue
Silver Spring, Maryland

Mr. Rahmoeller,

The Cordis Corporation has no sense of moral responsibility or interest in patient safety. Executive management constantly mandates that inferior product be produced without regard for quality or Federal Laws in order to meet production goals. This must stop! The executive officers of this company must take the blame since they are the cause. The enclosed information should be enough to convince you of their guilt. I have also sent information to various members of the U.S. Senate who by their past actions have indicated an interest in exposing corrupt medical companies. I also suggest that you investigate their MRR system which allows hundreds of inferior components to be used daily and their 190A series pacers which have a deadly hidden flaw in them. Cordis has lied to you on this and other problems.

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION	DISTRICT ADDRESS 7200 Lake Ellenor Dr. Suite 120 Orlando, Fl. 32809
NAME OF INDIVIDUAL TO WHOM REPORT ISSUED TO: HAROLD HERSHENSON	DATE OF INSPECTION 4/4-5/15/84
	C. F. NUMBER
TITLE OF INDIVIDUAL Executive Vice President	TYPE ESTABLISHMENT INSPECTED (i.e. bakery, cannery, etc.) Device Manufacturer
FIRM NAME Cordis Corporation	NAME OF FIRM, BRANCH OR UNIT INSPECTED Same
STREET ADDRESS 10555 W. Flagler St.	STREET ADDRESS OF PREMISES INSPECTED Same
CITY AND STATE Miami, Fl. 33172	CITY AND STATE Same

DURING AN INSPECTION OF YOUR FIRM (I) (~~WE~~) OBSERVED:

1. (a) On October 3, 1980, H. Tataria and F. Artelaez, requested through Service Request #80-10-002, 302756 that a study involving 200 Gamma cells be carried out by the Qualification Laboratory whereby 20 cells each were to be stored at temperatures of 25°, 30°, 40°, 50°, 60°, 70°, 75°, 80°, 85° & 90° C, with 10 cells in each group to be placed on 100K load and the remaining cells kept at no load. The Service Request description reads "Store the Gamma cells as shown below to characterise feedthrough at different temp. Read voltage once a week until 1.0 volt is reached."

Reportedly, no written reports were prepared concerning this study during its duration. The study was terminated on October 7, 1982. As a result of the large number of Gamma pacer field failures attributed to early battery depletion in middle of 1983, this data was resurrected and evaluated as described in a memorandum dated December 19, 1983, from R.D. Gjertson, which states, in effect, that based on the 200 cell test data, the predicted Mean Time to Failure extrapolated to 37° C (body temperature) is 32.1 months. This memorandum also states that, "Accelerated thermal life testing has shown a very high degree of correlation to body use conditions."

There is no written documentation which explains why the data generated from this 200 cell study was not evaluated until the middle of 1983 considering that significant data may have been available earlier.

The following chart lists examples of the cells in the study that failed:

Temperature °C	Cell #	Unloaded Voltage Reading (Spec. 2.14-2.20)	100K Load Voltage Reading	Date
50	194	2.076		10/15/81
50	191	2.097		10/22/81
50	220		2.083	10/22/81
60	434		2.078	4/30/81
60	387		.0180	6/4/81
60	320	2.099		6/18/81

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Victor Spaniol	EMPLOYEE(S) NAME AND TITLE (Print or Type) Victor Spanioli, Investigator

FORM FDA 483 (12/78) PREVIOUS EDITION MAY BE USED. INSPECTIONAL OBSERVATIONS PAGE 1 OF 4 PAGES

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION	DISTRICT ADDRESS 7200 Lake Ellenor Dr. Suite 120 Orlando, Fl. 32809
NAME OF INDIVIDUAL TO WHOM REPORT ISSUED TO: Harold Hershenson	DATE OF INSPECTION 4/4/83-5/15/83
TITLE OF INDIVIDUAL Executive Vice President	TYPE ESTABLISHMENT INSPECTED (i.e. bakery, cannery) Device Manufacturer
FIRM NAME Cordis Corporation	NAME OF FIRM, BRANCH OR UNIT INSPECTED Same
STREET ADDRESS 10555 W. Flagler St.	STREET ADDRESS OF PREMISES INSPECTED Same
CITY AND STATE Miami, Fl. 33172	CITY AND STATE Same

C. F. NUMBER

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

70	200	2.062		12/31/80
70	369	2.075		1/22/81
70	226		2.055	2/5/81
75	154	2.095		1/8/81
75	179		2.099	1/8/81
75	486	2.088		1/15/81
80	344	2.087		12/11/80
80	382	2.094		12/18/80
80	406	2.094		12/22/80
85	93		1.994	12/1/80
85	410	2.085		12/5/80
85	70		2.075	12/5/80
90	311		2.032	12/4/80
90	128		2.092	12/4/80
90	304	2.020		12/8/80

(b) Of the approximately 140 cells that were kept on this test until failure, only seven were destructively analyzed to determine the cause of failure. These seven cells were analyzed on August 18, 1983, and were found to have in excess of 40% glass corrosion.

(c) The batch number(s) of these cells is not recorded with the test data.

2. (a) Production Delivery Slip dated November 3, 1980, pertains to the shipment of 351 Gamma cells (lot 4180A) from the battery manufacturing plant to the pacer production line. This lot included both cells with and without polypropylene protected feedthroughs. However, the polypropylene protection to the cell feedthrough was not approved until April 6, 1981, as shown in the Qualification Laboratory Report (#80-10-003). There is no documentation to show that pacers manufactured with these cells were not distributed prior to the approval date of the polypropylene qualification.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS
7200 Lake Ellenor Dr., Suite 120
Orlando, Fl. 32809

NAME OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: HAROLD HERSHENSON

DATE OF INSPECTION

C. F. NUMBER

TITLE OF INDIVIDUAL
Executive Vice President

TYPE ESTABLISHMENT INSPECTED (i.e. factory, cannery)
Medical Device Manufacturer

FIRM NAME
Cordis Corporation

NAME OF FIRM, BRANCH OR UNIT INSPECTED
SAME

STREET ADDRESS
10555 W. Flagler St.

STREET ADDRESS OF PREMISES INSPECTED
"

CITY AND STATE
Miami, Fl. 33172

CITY AND STATE
"

DURING AN INSPECTION OF YOUR FIRM (I) ~~(WE)~~ OBSERVED:

* The dates of this inspection are as follows: 4/16,17,~~20~~/84; 5/29-30/84; 6/1,4,5,7,12,13,15,21,22,26/84.

1. (a) Although Cordis' position prior to this inspection has been that FDA was provided all reports of studies relating to feedthrough corrosion and decrease in resistance, reports pertaining to the analysis of reserve cells showing feedthrough corrosion and self-discharge were provided on June 15, 1984, only after they were specifically requested.

(b) The degree of feedthrough corrosion reported in the above studies for some of the feedthroughs that were examined is less than the amount of corrosion entered in the Laboratory Notebook. For example, the percentage amount of corrosion shown in the report for cell # 4280-1910 (Technical Report # 23-03888) is "< 5" whereas the amount of corrosion shown in the Laboratory Notebook for this cell (Laboratory Notebook # PA-303, page 29) is 22% on the right and 18.6% on the left. The reason for this and other similar discrepancies is not documented in the reports or the Laboratory Notebook.

2. Documentation Change Notice/Production Control Release #ME17848 dated October 3, 1980, requested by Brian Garrison shows that "urgent" was marked in the "Priority" portion of the form with the change relating to the addition of polypropylene to protect Gamma cell feedthroughs. Documentation Change Request (Change #ME17848) dated October 2, 1980, includes several indicators that emphasized the urgency of the change, such as "Hot Push" in the upper right hand corner of the form. The "Priority" block shows an oversized "X" in the "Urgent-Displace Other Jobs" category with two exclamation points placed to the left of the "X". The words "PLEASE EXPEDITE", underlined five times, appear in the "Request" section of the form. The "Reason" for the Documentation Change Request is shown as "Product Improvement (Explain)". However, no explanation is provided as to the nature of the improvement.

3. Technical Report #23-03703 dated March 18, 1983, pertaining to the analysis of reserve cell 1181-1054 and reserve cell 1980-029 states that "It is believed that these cells may have rapidly depleted after the formation of conductive, copper-containing dendrites which shorted the anode and cathode directly." However, the post #130 reserve sample EBD's listing shows that the cause of failure is "undetermined".

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE

EMPLOYEE(S) NAME AND TITLE (Print or Type)
Victor Spanioli, Investigator

FORM FDA 483 (12/78) PREVIOUS EDITION MAY BE USED. INSPECTIONAL OBSERVATIONS PAGE 1 OF 4 PAGES

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION	DISTRICT ADDRESS 7200 Lake Ellenor Dr., Suite 120 Orlando, Fl. 32809
NAME OF INDIVIDUAL TO WHOM REPORT ISSUED TO: HAROLD HERSHENSON	DATE OF INSPECTION See Page 1
	C. F. NUMBER
TITLE OF INDIVIDUAL Executive Vice President	TYPE ESTABLISHMENT INSPECTED (i.e. bakery, cannery) Medical Device Manufacturer
FIRM NAME Cordis Corporation	NAME OF FIRM, BRANCH OR UNIT INSPECTED Same
STREET ADDRESS 10555 W. Flagler St.	STREET ADDRESS OF PREMISES INSPECTED Same
CITY AND STATE Miami, Fl. 33172	CITY AND STATE Same

DURING AN INSPECTION OF YOUR FIRM (I) ~~(WE)~~ OBSERVED:

4. (a) In response to an FDA request on May 2, 1984, Cordis legal files pertaining to allegations of product failure were reviewed. Based on this review a total of 49 cases dating from 1977 to the present involving either lawsuits, intents to sue, or requests for reimbursement for medical costs, were identified that had not been documented as product complaints, and therefore, were not accessible for review by FDA during inspections. These complaints, involving pacers, leads, Hakim valves, catheters, and Flow Rate Injectors, involved 16 cases where only product failure was alleged, 28 cases were injuries or hazards were reported (this group includes vague allegations of adverse affects such as "pain and suffering", "physical and emotional trauma", etc.) and five cases in which a death was reported.

(b) The Product Service Department has not evaluated all of these complaints to determine what followup is necessary.

(c) Cordis has stated that there are approximately 50 to 150 additional complaints received by the Legal Department since 1977 that are being reviewed to determine if the Product Service Reports, that had been originally completed based on product returns, include reference to all information concerning product performance and any hazards associated with product failure that are discussed in the complaints.

5. (a) A 510(k) Notification relative to the addition of polypropylene in Gamma cell feedthroughs initiated with lot 4180, cell 267 (October 1980), and the addition of polyimide to Gamma cell feedthroughs initiated with lot 2082 (May 1982), was not submitted until after FDA requested a retrospective 510(k) Notification for the polypropylene and polyimide changes on December 7, 1983.

(b) A 510(k) Notification has not been submitted for the Model 340A (Mini-Gamma) pacer.

6. (a) Cordis did not notify FDA of any of the "cross talk" complaints including one complaint which resulted in a pacer explant (415A-1561). Prior to this inspection, no investigation had been conducted to determine why this pacer had been explanted. The Clinical Research Department had not been informed of this complaint by the Product Service Department.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)* Victor Spanioli, Investigator

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS
7200 Lake Ellenor Dr., Suite 120
Orlando, Fl. 32809

NAME OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Harold Hershenson

DATE OF INSPECTION
See Page 1

C. F. NUMBER

TITLE OF INDIVIDUAL
Executive Vice President

TYPE ESTABLISHMENT INSPECTED (i.e. bakery, cannery.)
Medical Device Manufacturer

FIRM NAME
Cordis Corporation

NAME OF FIRM, BRANCH OR UNIT INSPECTED
Same

STREET ADDRESS
10555 W. Flagler St.

STREET ADDRESS OF PREMISES INSPECTED
Same

CITY AND STATE
Miami, Fl. 33172

CITY AND STATE
Same

DURING AN INSPECTION OF YOUR FIRM (I) [redacted] OBSERVED:

(b) Cordis analysis of this explanted pacer did not confirm cross talk. However, the Engineering Analysis Laboratory did not receive a copy of the Cordis [illegible] report which discussed how the cross talk phenomenon could be duplicated in a suspect pacer. The Engineering Analysis Report for this pacer reveals that the pacer was not tested in accordance with the Cordis procedure developed to simulate cross talk.

(c) After the cross talk phenomenon was characterized by Cordis and clinical records reviewed to determine if other patients had experienced this phenomenon, (3 cases were found), physicians were notified; however, there is no documentation concerning this telephone notification.

(d) At an American Heart Association Scientific Session held November 14-17, 1983, B. Beaver, M.D., reported on the crosstalk phenomenon involving four patients implanted with the Cordis model 415A pacer in which one patient experienced an episode of syncope. An abstract of Dr. Beaver's presentation was available to Cordis which discussed the one episode of syncope. No investigation was conducted prior to this inspection regarding this report of syncope.

(e) A total of 187 cases have been identified by Cordis involving instances in which the model 415A pacer has a dual anodal-ring configuration and in which competitors leads are used. ~~Prior to this inspection~~ No action had been taken to advise the monitoring physicians of the potential cross talk phenomenon.

7. (a) With respect to Temporary Authority (TA) 70616 dated July 1, 1983, relating to the reduction in Receiving Inspection testing for Gamma, Gemini, and Sequicor Hybrids from 100% to 25%, FDA was not notified of this change.

(b) During an evaluation of this TA by Regulatory Affairs on or about July 26, 1983, it was determined that hybrid test set #10 "was giving numerous unexplained failures which required retest on another test set". In spite of this, the test set continued to be used.

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE

EMPLOYEE(S) NAME AND TITLE (*Print or Type*)
Victor Spanioli, Investigator

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Memorandum

Date

From Don F. Dahms, HFZ-450
Through: Glenn A. Rahmoeller 5/2/84

Subject Cordis Anonymous Letter

To W.H. Damaska, HFZ-324

See the attached evaluation of the exhibits.

Donald F Dahms
Donald F. Dahms

Evaluation of Exhibits

The following is a evaluation of the documents that were included in the anonymous letter containing allegations of regulatory impropriety by Cordis Corporation.

Exhibit 1

Allowing pulse generators to be assembled with hybrid circuits that received 25% rather than 100% testing violates the PMA's for Gemini (P830007) Sequicor Model 233D/E (P820014) Model 233F (P820014/S2) and Model 233 G(P820014/S3). All documents explicitly required 100% testing of all hybrid circuts. FDA was not informed. Health impact is unknown, but is potentially serious.

Exhibit 2

Model 233E Sequicor pulse generator has a ventricular refractory period between 286 and 297 milliseconds as stated in the labeling (Physician's Manual). This exhibit allows a refractory of 283 to 285 milliseconds in violation of the approved labeling. The health impact is minimal. FDA was not informed of this change.

Exhibit 3

This exhibit allows a slightly lower minimum (3%) and slightly higher maximum (2%) output current than specified in the approved test. These limits are reflected in the tolerances in the labeling. FDA was not informed of this change. The health impact is minimal.

Exhibit 4

Voltages which determine the initiation of the end of life (E.O.L.) indicators are not specified in the PMA application. No ratio of time between operation at 62 1/2 pulses per minutes (ppm) and 52 1/2 ppm is specified. The operation time for both rates combined is 6 months, which is the span of the EOL indicator.

This issue was discussed with FDA.

Exhibit 5

Indicates that a Gamma Cell was used in the manufacture of the Sequicor Pulse Generator Model 233E. This change was not approved by FDA. Health impact is unknown.

Exhibit 6 and 7

The change in test limits of output current was not submitted to FDA as of the date of the Exhibit (3/15/83). A change was submitted on the subject in the Autumn of 1983.

The programmer software change was not reported to FDA. The need for programming the back-up mode to "OFF" separately from the "STATSET" function would create confusion in the use of the device.

Exhibit 8

These tests were not specifically mentioned in the PMA applications. Specifying 47° C as the test temperature rather than 37°C and specifying different pre and post burn-in test battery voltages does seem to be a manipulation of the screening process. The consequences of this cannot be determined from the data in this exhibit.

Exhibit 9

This program change, which may be related to Exhibits 6 and 7, was not reported to FDA.

Exhibit 13

2 These changes in software and instructions for use were not submitted to FDA.

Exhibit 14

The change in the hybrid for Gemini may have been submitted in P830007/S2 dated 12/7/83 and P830007/S3 dated 1/13/84.

The change in the cell type used was not mentioned in the submission.

Exhibit 15

The package configuration change was not submitted to FDA.

Exhibit 16

The change in capacitor value was not submitted to FDA.

Exhibit 17

The significance of this change in the end of life rate test cannot be evaluated without further explanation. No information was submitted to FDA on this subject.

Exhibit 19

The approved battery for Gemini 418A and Sequicor 233GL is rated at 1.01 Ampere-hours.

Exhibit 23, 24 and 26

These exhibits relate to adverse experiences. No adverse experience reports have been received for any Cordis pulse generators.

Donald F. Dahms

Donald F. Dahms

Memorandum

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

*VOID

TO : Director, National Center for Devices
and Radiological Health, HFZ-1

DATE: May 14, 1984

FROM : Director
Orlando District, HFR-4200

Manufacturer: Cordis Corporation
P.O. Box 025700
Miami, FL 33102

SUBJECT: On-going Investigation

Cordis Corporation currently is involved with a Class I Recall Notification concerning its Gamma pacemakers due to early battery depletion which involves self-discharge related to unprotected feedthroughs in Cordis manufactured power cells. Our investigation of Cordis and its operations has been ongoing since December 3, 1983.

On April 2, 1984, the Inspectional Observations relating to early battery depletion in Gamma pacers was issued to Norman R. Weldon, Ph.D., President. At the time the Inspectional Observations were issued to Dr. Weldon, he stated that the items listed on the Inspectional Observations relating to Cordis being aware in 1980 that their Gamma pacers would fail early and the firm continuing to distribute these pacers, were interesting in that a similar message was getting out to competitor firms. Dr. Weldon stated that he was concerned that observations on the FDA-483 may be made available to industry competitors either by FDA or individuals from Cordis. He also stated his concern that FDA had received a copy of the "Special Audit - Gamma Battery Cell Depletions" conducted by Cordis in September 1983. He explained that Cordis was considering hiring a private investigator in an attempt to establish who is leaking the confidential information from within Cordis and requested FDA cooperation in this investigation. Dr. Weldon was unable to stay for the complete discussion of the List of Observations, and had to leave after approximately one hour, after which time he commented he would leave the FDA-483 in the conference area because he didn't even want it laying around in his office.

We have learned that towards the end of November 1983, Cordis reportedly received an anonymous letter having an FDA letterhead advising the firm that a copy of the "Special Audit - Gamma Battery Cell Depletions" had been received at the FDA. Reportedly, this anonymous letter was from an FDA employee whose mother had a Cordis pacemaker implanted. This letter reportedly had a Prince Georges County post office postmark.

*(Note: the memo was never forwarded to the addressee and is considered VOID by the District)

Buy U.S. Savings Bonds Regularly on the Payroll Savings Plan

Another anonymous letter, according to Dr. Weldon, having an FDA letterhead was reportedly received by him and reportedly stated that based upon information FDA had obtained from a Cordis employee (the name of this employee was reportedly specified) a full FDA investigation of Cordis was warranted. Reportedly, this letter was prepared by a Mr. Baxter (phonetic spelling and exact name uncertain) to Mr. Villforth and was reportedly copied from Mr. Villforth's circulating file.

Another anonymous letter, according to Mr. Weldon, was sent to Cordis from FDA stating that the Agency had received another anonymous complaint with a large number of Cordis in-house documents attached. We learned of this on April 16, 1984, when we met with Dr. Weldon to inform him that we intended to broaden our investigation based on complaints we had received. At this time we informed Dr. Weldon of the general areas we intended to pursue relating to allegations involving the firm's physiological pacers, programmers, and batteries. Dr. Weldon was not surprised and stated that he was aware of our areas of interest for he had already received a confidential letter from an anonymous FDA source informing him of our interest in these areas.

We requested copies of the two documents Dr. Weldon has referred to as being received anonymously at Cordis from FDA, but he has refused to provide these or even discuss them in any detail. Therefore, we are not certain of the existence of these anonymous letters or, for that matter, that they were ever received. Our Miami Resident Post personnel do believe that Cordis has received at least one of the documents, possibly two, based, in part, on Dr. Weldon's reaction when we informed him that we intended to expand our investigation.

I am bringing this to your attention because we believe there may be some validity in the statements concerning the anonymous letters and, if such leaks are occurring, they could seriously hamper our ongoing investigations.

Adam J. Trujillo

/mal 5/14/84

cc: MIF/SAK

JUN - 5 1984

MAL - Pls assign M# 2

VJF - Pls request copy of 6/30/84 Cordis report

Pls visit legal dept & request directory & ask if any more complaints for [illegible] PSRs [illegible] have been identified.

JAC

e/cV

GREENFIELD, CHIMICLES & LEWIS
ATTORNEYS AT LAW
ONE HAVERFORD CENTRE
361 WEST LANCASTER AVENUE
HAVERFORD, PENNSYLVANIA 19041-0100
(215) 642-8500

RICHARD D. GREENFIELD*
NICHOLAS E. CHIMICLES
DONALD B. LEWIS
ROBERT P. FRUTKIN
CAROLE A. BRODERICK
E. STIRLING LATHROP, III
R. BRUCE MCNEW**
DAVID B. ZLOTNICK
SUSAN SCHNEIDER THOMAS
MARCY C. PANZER

*ALSO ADMITTED TO NEW YORK BAR
**ONLY ADMITTED TO DELAWARE BAR

June 1, 1984

Corporation 1016427
J.J.T.
5/22,29-31,6/1&5/84
Exhibit# 3 . Page 1 of 3 pps.

COMPANY CONFIDENTIAL

Board of Directors
Cordis Corporation
P. O. Box 525700
Miami, Florida 33152

Dear Sirs:

I am writing to you on behalf of our client, Mr. David Steinberg, a shareholder of the Company.

On behalf of Mr. Steinberg, we hereby demand that the Company take prompt legal action against each of the persons responsible for making false and misleading projections with respect to the Company's financial and operating condition for the fourth fiscal quarter ending June 30, 1984. The result of these false and misleading projections has been that the integrity for the market in the Company's securities has been violated and persons have sustained damages as a result thereof. It is fair to assume that one or more of such persons will assert claims against the Company to recover their damages and, possibly, as well as those of all other persons similarly situated.

In addition, on behalf of our client, I hereby demand that the Company take immediate legal action against each of the persons responsible for each of the activities which has led to the on-going investigation by the Food and Drug Administration of the Company's manufacturing, marketing and other practices, all of which has caused substantial expense to the Company, as well as damage to its reputation and its ability to conduct its business.

The foregoing has already resulted in substantial damages with the likelihood that the damages will continue to mount. Accordingly, unless prompt legal action is instituted by the Company, we have been authorized by our client to commence litigation derivatively on behalf of the Company against the persons responsible for the above activities.

Cordis Corporation 1016427
4/16-5/15/84 L.J.T.
5/22,29-31,6/1&5/84
Exhibit# 3 , Page 2 of 2 pps.

Board of Directors
Cordis Company
Page -2-

COMPANY CONFIDENTIAL

I shall look forward to hearing from you no later than June 30, 1984 to the effect that the Company has taken the foregoing action.

Sincerely yours,

Richard D. Greenfield

Richard D. Greenfield

RDG/ss

cc: Mr. David Steinberg

June 19, 1984

Commissioner of Social Security Administration
6401 Security Boulevard
Baltimore, Maryland 21235

Dear Sir:

The Orlando District of the Food and Drug Administration is currently evaluating and monitoring the effectiveness of a Class I recall of certain cardiac pacemakers by the Cordis Corporation, Miami, FL, because they have the potential to fail due to early battery depletion. This situation may expose pacemaker-dependent patients to life threatening situations or serious adverse health consequences.

It is customary for patients with implanted pacemakers to maintain contact with a monitoring physician who can advise them on the condition of their pacemakers. Three hundred fifty-four (354) patients with implanted pacemakers under recall have not maintained this contact. We have attempted to locate these individuals through sources available to us including the post office and telephone books, but have been unsuccessful. We are, therefore, requesting your assistance in determining current addresses for these patients so that the recalling firm may notify them of this potential serious problem as soon as possible. Enclosed is a list of these 354 patients and their social security numbers provided to us by the recalling firm. We would also appreciate your identifying any deceased individuals.

Thank you for your assistance in this important consumer protection effort. If you have any questions regarding this request, please contact me or Carl C. Reynolds, Director, Investigations Branch at FTS 820-6281.

Sincerely yours,

Edward R. Atkins
Acting Director
Orlando District

Enclosure

bcc: HFC-510
HFZ-321
HFR-4575/ MIA-RP
HFR-4200/ AJT Chron / Re file

TGForrest/CCReynolds/ERAtkins/al 6/19/84

[illegible]
Miami FL 33102-5700 USA
Telephone 305-551-2000
Telex 681112

Cordis

Dr. Weldon

June 21, 1984

Richard D. Greenfield, Esquire
Greenfield, Chimicles & Lewis
One Haverford Centre
361 West Lancaster Avenue
Haverford, PA 19041-0100

Dear Mr. Greenfield:

We have received your June 1, 1984 letter in which you assert a demand on behalf of your client, Mr. David Steinberg, that the Board of Directors of Cordis Corporation take "prompt legal action against each of the persons responsible" for developments adverse to the Company. It is not possible for the Board to accede to that request, or even to reject it, because the demand itself is wholly undefined. Your letter does not identify the persons against whom the Company has or may have a right of action. The letter does not state a legal theory upon which the Company might base such a lawsuit; nor does it contain facts that could be used to plead any legal theory against any person.

Be assured that the Board of Directors is monitoring the situation relating to the Food and Drug Administration and that the Board will take whatever steps it deems necessary to protect the Company's interests.

Sincerely,

Daniel G. Hall

Daniel G. Hall
Secretary and
General Counsel

DGH:as

cc: Board of Directors

✓

Memorandum of Meeting

Between
Norman R. Weldon, President
Cordis Corporation

Harold Hershenson, Executive Vice President
and President, Angiographic Products Division

John N. Pagones, Vice President, Corporate Product Assurance

and

James A. Casey, Supervisory Investigator
Miami Resident Post, FDA

Victor Spanioli, Investigator
Miami Resident Post, FDA

June 22, 1984

A meeting was held at Cordis Corporation, 10555 West Flagler St., Miami, FL 33172, on Friday, June 22, 1984, at approximately 9:00 a.m. involving the above individuals.

At the onset of the meeting Dr. Weldon stated that Cordis had prepared a response which expressed their position with respect to whether or not Cordis should, at this time, withhold from sale any pacers that have cells with the polypropylene design (feedthroughs) change. The polypropylene design change requires coverage of the glass feedthrough insulator with heat melted polypropylene which is mechanically held in place by heat shrink polypropylene slipped over the feedthrough pin. This response is in the form of a letter to Mr. Trujillo dated June 22, 1984, a copy of which is submitted as Attachment #1.

Mr. Hershenson began the discussion by stating that Cordis disagrees that pacers currently in inventory or on consignment which have polypropylene protected cells should be quarantined, as all reliability information available to Cordis, including field reports, life test pacer data, and accelerated studies show that the polypropylene group is performing satisfactorily. In addition, Mr. Hershenson stated that life test reserve cell failures have occurred only in lots 4280 and 4380 and there have been no failures in any other polypropylene protected cell lots manufactured in 1980. Mr. Hershenson and Mr. Pagones both stated that the failures in lots 4280 and 4380 are attributed to a "learning curve" in the application of polypropylene to the feedthrough insulator by employees. Mr. Pagones stated that no correlation has been found between the number of failures occurring in lots #280 and #380 and any common factor; therefore, the firm has concluded that the adequacy of polypropylene application in these two lots is dependent on employee application technique.

Mr. Hershenson stated that the failures experienced thus far relating to polypropylene involve situations in which the heat shrink polypropylene was either under-applied or over-applied onto the hot melt polypropylene covering the feedthrough glass, thereby resulting in an inadequate seal which allowed electrolyte contact with the glass.

Dr. Weldon stated that there is currently no basis for notifying physicians on pacers having polypropylene protected cells. Dr. Weldon stated that Cordis is very much aware of FDA's concern and they are even more concerned about the same issues. He stated that physicians can understand a notification if failures have been experienced; however, the cumulative survival of pacers having cells with the the polypropylene design change is 99.2% and physicians would not be able to understand why notification is necessary for pacers achieving such a high degree of reliability. Moreover, Dr. Weldon stated that Cordis would prefer to notify in cases in which they are aware of a defective or potentially defective product rather than having competitors disseminate information about problems involving Cordis products.

Mr. Pagones stated that the initial projected or predicted cumulative survival (reliability) rate for all Gamma series pacers was approximately 95% at sixty months (5 years) but that the trend starts downward as the pacers approach the 5 year period.

Mr. Casey interjected that the Food and Drug Administration had reclassified the Medtronic's polyurethane lead notification from Class II to Class I. Dr. Weldon stated that, unfortunately, this would adversely affect Cordis from the standpoint that physicians would be less inclined to use all polyurethane leads, which includes the Cordis lead most preferred at the present, in spite of the fact that Medtronic has identified certain polyurethane materials that have been shown not to be susceptible to degradation and noted that the Cordis polyurethane material is of the type subject to degradation.

Mr. Casey next asked about the distribution of the Cordis Product Updates and whether or not this was the desired form of communications to physicians when Cordis has an important message to convey. Mr. Hershenson stated that the most effective means is to have the salesmen carry the written information to physicians and then discuss it with them. Mr. Hershenson added that approximately 15,000 physicians receive the Product Updates.

Investigator Spanioli asked why the firm had decided to eliminate from the Lambda series Product Update any reference to Lambda associated failures such as early battery depletion and printed wiring board failures. Mr. Pagones responded by stating that this information had been conveyed to physicians in prior editions of the Product Update and there was no need to continue to repeat the same information in the April 1984 issuance. Mr. Casey stated that in his judgment, the Product Updates do not constitute adequate notification to physicians on significant problems such as the printed wiring board failures in Lambda and Theta pacers. Moreover, to compound the situation, Cordis has even omitted mentioning this sudden failure or malfunction problem from the last Product Updates sent to physicians.

Mr. Casey commented in reply to the learning curve comment on the polypropylene application that it may not be practical in a production environment to apply the polypropylene to the feedthrough insulator because of the difficulty in obtaining a complete seal. Mr. Hershenson stated that they agree that the polypropylene is not "perfect"; however, as in vitro data, field data, and the 99.2% cumulative survival data at 42 months show, the group of pacers with the polypropylene protected cells has performed satisfactorily and there is no basis to think that the group will not perform satisfactorily in the future. Mr. Casey asked if the cumulative survival data and curve attached to the June 22, 1984, response included both the polyimide and polypropylene design changes under "protected cells" and Mr. Hershenson stated that they did. Mr. Casey explained that our concerns are expressly connected with the polypropylene design change and requested that all future updates only include data on the polypropylene cells since this was the area of concern at the present time; not the polyimide protected cells. Mr. Hershenson stated that he was not certain this was possible but that he would check.

Dr. Weldon and Mr. Hershenson next discussed the performance of battery lots 4280 and 4380 which have a cumulative survival, with respect to battery depletion failures of 97.5% at 41 months and 96.0% at 41 months, respectively. They stated that this is of extreme concern and the performance of these two lots is being carefully followed. Dr. Weldon stated that if the monthly failure rate approaches 0.100%, then this would be important and a decision would have to be made to notify physicians on the performance of these two lots. Page 5 of Attachment #1, shows that the monthly early battery depletion failure rate for lots 4280 and 4380 is 0.046% and 0.024%, respectively.

Mr. Casey also asked if the cumulative survival data and total implant months was derived by including data on explanted pacers, that Cordis was not aware of, as a survival, thereby improperly increasing the total months of implants for the statistical cumulative survival data base. Mr. Hershenson stated that this was true but that Cordis had conducted studies in the past and that thhese explanted pacers of which they were not aware did not affect the cumulative survival results much and that Cordis also used the Billitch Reports for comparative purposes.

A discussion then was held as to whether or not the initial survival projections or trends for a pacer are ever changed during its marketing. This question initially was not answered directly and it was explained that the projections differ for each pacer model. Mr. Hershenson finally stated that the initial projections are never changed.

Investigator Spanioli then discussed the results of analysis pertaining to life test reserve cells manufactured from late 1980 until Mid-1982. The conclusion, based on the analysis of these cells, as stated in Task Force Report #1 dated September 15, 1983, was that although corrosion was significantly reduced, the degree of self-discharge was not similarly significantly reduced in that 45% of the population having polypropylene protection exhibited signs of self-discharge. Dr. Weldon, Mr. Hershenson, and Mr. Pagones stated that they were not familiar with the data presented in these reports and that they would need to review this information to determine if it would impact on the decision that they have reached thus far with respect to the status of pacers in inventory or on consignment that have been identified as containing cells with polypropylene protection. Dr. Weldon subsequently commented that he ought not to sign documents, referring to his letter to Mr. Trujillo, if he does not have available to him all information in Cordis' possession that would influence him in reaching a decision.

After the meeting, Mr. Oscar Jiminez advised Investigator Spanioli that he had made an error in his interpretation of the life test reserve cell analysis reports in that he did not consider the amount of discharge that would have occurred by virtue of the cells being under load for two to three years. Mr. Jimenez will amend the Task Force Report and provide a copy to FDA.

Supervisory Investigator Casey requested, as he had previously discussed with Mr. Pagones, that Cordis prepare a complete listing which would provide all test groupings and dates pertaining to all Cordis studies which relate to early battery depletion or polypropylene protection. Mr. Hershenson and Mr. Pagones responded by stating that as far as they knew, all documentation relating to polypropylene protection feedthrough studies had already been provided to the Food and Drug Administration. After further discussion concerning the future misunderstanding which could occur if such a listing was not provided, Mr. Hershenson agreed that a complete listing of all documents relating to polypropylene protection studies conducted by Cordis would be prepared for FDA. In addition, copies of three summaries, listing feedthrough corrosion/resistance studies, prepared for Mr. Hershenson, at his request, to ensure that there were no reports that were not brought to his attention, would be provided to FDA. Mr. Casey stated that such a listing was necessary to prevent further breakdown in communications and that, in his judgment, corporate management should want such a listing to assure that they are aware of all such testing related to the polypropylene design change.

Mr. Casey pointed out that during the December 22, 1983, meeting at Cordis with Mr. Pagones that all testing and audits conducted by the firm as a result of the formation of the Task Force on early battery depletion were specifically requested.

Supervisory Investigator Casey stated that the firm had not yet received approval from the Food and Drug Administration with respect to the marketing of pacers incorporating power cells with polypropylene protected feedthroughs and emphasized that the Agency needed to assure that all documents relating to testing the adequacy of polypropylene feedthrough protection were identified and furnished to the Agency to prevent any future misunderstandings. Mr. Casey stated that all testing had not been mentioned in the 510(k) Notification. As an example, Mr. Hershenson was reminded of the reserve cell study conducted by the firm as part of the Task Force investigation which had not been provided to FDA until it was specifically requested although Cordis management had made several statements that all such study reports relating to the adequacy of the polypropylene protected feedthroughs had been provided. Mr. Hershenson stated that the in vitro pacer data is more significant than the in vitro reserve cell data in that the reserve cells could have been shorted through mishandling either during storage or while being tested.

Mr. Casey asked if a corporate decision or cutoff point in regards to failures associated in the polypropylene design cells had been decided upon at which time the firm would notify physicians of a problem. A direct answer was not provided but Mr. Hershenson replied that all data available would have to be considered.

Subsequently, Mr. Casey stated that he perceived a reluctance on Cordis' part to prepare a listing of all reports relating to polypropylene protection studies. Mr. Hershenson stated that he would provide a listing of all the test reports used to compile the data to support the findings in the attachments to the June 22, 1984, memorandum, attached. Mr. Casey replied that he was requesting a complete listing of all tests conducted on the early battery depletion problem and design changes and if such a listing was limited to those tests supporting the data in the attachments to the June 22, 1980, response, that in his judgment a good faith effort would not have been shown by Cordis Corporation.

Mr. Casey pointed out that during the December 22, 1983, meeting at Cordis with Mr. Pagones that all testing and audits conducted by the firm as a result of the formation of the Task Force on early battery depletion were specifically requested.

Mr. Hershenson and Mr. Pagones stated that they will provide monthly reports concerning the reliability of the protected cells to the Food and Drug Administration to ensure that the Agency is kept abreast of this information. Mr. Casey asked that this data only include cells incorporating the polypropylene design change and that the polyimide protected cells be omitted. Dr. Weldon stated that he would be concerned if the cumulative survival is less than the 98% after 42 months for the protected group. Mr. Casey stated that he disagreed that the majority of pacers incorporating the polypropylene design feedthrough changes are adequately protected based on preliminary data, but that time should provide more meaningful data on which to reach a conclusion.

Mr. Casey explained the results relating to the amount of corrosion observed in reserve cells that were analyzed as part of the Task Force investigation on early battery depletion. The point raised was that the Summary Technical Reports showed a lower feedthrough corrosion than the corresponding laboratory notebook entries in some, but not all, cases. Mr. Hershenson and Mr. Pagones stated they were not previously aware of the differences and that this was surprising. Mr. Hershenson stated the differences would have to be evaluated to determine if there were justifiable explanations.

Mr. Casey stated that the 510(k) notification concerning the polypropylene and polyimide protection of Cordis Gamma cell feedthroughs should have been submitted to the Agency prior to the changes in the feedthrough design being implemented. Mr. Hershenson stated that this was arguable as it had been the Agency's position through Vic Zafra's statements to industry that the Agency did not want 510(k)'s on every single design change. Mr. Casey stated that this was true for insignificant changes but that 510(k)'s were required prior to implementing significant changes or other commitments previously made in writing to the Agency. Dr. Weldon ultimately stated "you got a point" in response to Mr. Casey's statement.

Mr. Casey stated that it appeared that accelerated testing of pacers incorporating the polypropylene design feedthrough changes consistently gave better survival rates than pacers undergoing life testing. Mr. Hershenson stated that the high temperatures in the accelerated tests should be a driving force for Lithium activity resulting in increased corrosion. Investigator Spanioli pointed out that only two of post 4280 cell lots having polypropylene protection were included in the accelerated testing; therefore, the results may not be statistically meaninfgul to gauge the performance of the entire population.

During the discussion about whether or not the firm should have submitted a 510(k) Notification prior to the polypropylene and polyimide cell design changes, Dr. Weldon stated that he had recently been interviewed by Senate Committee on Aging staff members and asked if he thought that FDA was doing a good job. He stated that he thought that the FDA could be torn apart by Congress if they so chose, not because of their staff, but because the Agency's overall task is impossible. Dr. Weldon stated that one of the major problems confronting FDA concerns computer software that is frequently changing and could result in people getting killed due to problems with software related device failures. Dr. Weldon was informed of the efforts undertaken by FDA to train their investigators in this area. Dr. Weldon stated that the Agency did not have a chance in learning about and keeping abreast of software technology as Cordis can't even train their own engineers fast enough to keep up with the new advances in software technology as software changes are occurring at a very rapid pace.

Mr. Casey asked Dr. Weldon what was the nature of the meeting with Senate staff members. Dr. Weldon stated that it was not directly related to the ongoing Cordis investigation; however, pointed out that he was asked several questions about the ongoing inspection. Dr. Weldon stated that there were no comments from him that were derogatory towards FDA with respect to how the inspection was being handled.

Dr. Weldon stated that the reason for his meeting with the staff members the Senate Committee on Aging was a followup to the investigation initiated two years ago relating to the extent of corruption in the pacemaker industry.

Mr. Casey stated that he believed the battery industry may have designed their cells beginning as early as 1977 to protect the feedthroughs from degradation. Dr. Weldon and Mr. Hershenson acknowledged that this was the case and gave the impression that their cell design should have also similarly been protected at its inception.

A discussion next ensued about the stimulus behind FDA's extensive investigation at Cordis. Dr. Weldon stating that it was clear in his mind that the lengthy investigation was prompted by the Medtronic polyurethane leads situation and the subsequent criticism by Congress in the manner that FDA addressed the Medtronics problem. Dr. Weldon was informed that the Medtronic case had nothing whatsoever to do with the ongoing Cordis inspections as the thrust of our inspections have been based on information received by FDA about Cordis activities and also by information and deficiencies documented while conducting the inspections. Mr. Casey explained that our investigations have revealed a continuing pattern of Cordis identifying problems involving devices such as pacers and leads for which, based possibly on economic judgments, no action was taken concerning the devices that remained in inventory at the time manufacturing changes were implemented to correct the problem or defect. Dr. Weldon and Mr. Hershenson stated that this was an unfair characterization of what happened. Dr. Weldon stated that those decisions could be called "retrospective errors in judgment"; however, the decisions at the time were not based on economic considerations.

Mr. Casey then discussed the Orlando District followup investigation involving allegations made by a Cordis salesman that an FDA Philadelphia District Investigator had erroneously stated that the model 190A pacer was subject to recall. Mr. Casey stated that the District had looked into this matter and had determined that the allegations were unfounded. Mr. Casey stated that he was confident the FDA Investigator had not made the alleged statement and if the firm was not satisfied with how this situation was handled then they were welcome to write a letter to the District or anyone else stating their concerns. Dr. Weldon, Mr. Hershenson, and Mr. Pagones stated that they have no desire to pursue this any further, that they were satisfied with the response, and were appreciative of the fact that the Orlando District had pursued the allegations and the matter had been resolved. Dr. Weldon stated that the matter was settled and no further action was contemplated.

Mr. Casey then discussed the status of the lost to followup patients with reference to the Gamma Notification. Mr. Casey stated that the District was preparing a request to the Social Security Administration and was considering possible additional contact with Internal Revenue Service which would be based on the success of the efforts from Social Security concerning the lost to followup patients.

Mr. Casey then asked Mr. Hershenson if there were any commitments that he had made to Cordis that he had not fulfilled. Mr. Hershenson stated to Mr. Casey that he had fulfilled all of his commitments.

Dr. Weldon next initiated a discussion on the changes that Cordis had made in response to FDA 483 observations. Mr. Pagones stated that the firm had made a number of procedural changes, as well as introducing a new Product Service Report form. Mr. Hershenson stated that the firm is considering eliminating guard bands from their specifications, even though this would increase cost in that component failures would be detected at latter stages of production. However, he added, this would eliminate a lot of paperwork related problems. Dr. Weldon stated that one of his concerns is that the company is more vulnerable at the present in making product quality mistakes because a number of Quality Assurance personnel have been involved in responding to FDA 483 observations. Dr. Weldon acknowledged that Mr. Pagones' Product Assurance Department is understaffed as he (Weldon) had fired three people from that Department.

Mr. Casey commented that he could not understand why Cordis had not hired replacements for these three individuals as the experience gained over the last six months by the replacements would have been invaluable. Mr. Casey added that he was of the opinion that Cordis may be trying to deliberately delay FDA completion of the investigations in a timely manner for unknown reasons. Dr. Weldon and Mr. Hershenson stated that this was not the case.

Mr. Casey discussed another area of concern which related to the fact that complaints being received by the legal department were not maintained as part of the complaint or Product Service Report handling system. Mr. Hershenson stated that those complaints should have been included in the complaint handling system. Dr. Weldon stated that the firm had overlooked the idea that the legal department was a source of complaint information. Mr. Casey also pointed out that FDA was still waiting to receive information on 50 to 100 additional complaints which may or may not have been previously reported in the complaint system.

Mr. Casey asked the Cordis representatives if they were aware that a pacer subject to 115° C gas analysis was subsequently distributed, implanted and explanted after approximately three months. They indicated that they were not aware of this incident and expressed surprise. Mr. Hershenson stated that this would not be possible because a hole had to be drilled in the pacer during the gas analysis test procedure. Mr. Casey stated that the incidence did happen and that it would be an item on Investigator Spanioli's next Inspectional Observations.

At the conclusion of the meeting, Dr. Weldon requested that he meet privately with Mr. Casey. A separate memorandum discusses Mr. Casey's meeting with Dr. Weldon.

Victor Spanioli

James A. Casey

James A. Casey

Orig: ORL-DO/CCR for HFR-4250 w/attach.
cc: HFR-4575 w/attach.
cc: HFZ-320 w/attach.

Memorandum of Meeting

Between

Norman R. Weldon, Ph.D.
President, Cordis Corporation

and

James A. Casey, Supervisory Investigator
Miami Resident Post
Food and Drug Administration

June 22, 1984

On this date, Investigator Victor Spanioli and I met with Dr. Norman R. Weldon, President, Mr. Harold Hershenson, Executive Vice President, and John N. Pagones, Vice President, Corporate Product Assurance, to discuss our stated concerns relating to the adequacy of the approximate 20,000 polypropylene protected feedthrough pacemakers currently implanted and being marketed which are not covered by the Notification Letter dated December 5, 1983. On the basis of the foregoing meeting and written response prepared by Cordis, they concluded that polypropylene feedthrough protection is highly effective in preventing early battery depletion in hermetic lithium cupric sulfide cells, and that no action is required on their part at this time other than to monitor all pacers with polypropylene protected seals and provide monthly reports to the Food and Drug Administration.

Dr. Weldon, at the conclusion of the meeting, requested that he meet with me privately and I honored his request. This memorandum covers discussions held with Dr. Weldon, both after the meeting and during the meeting. A separate memorandum is being prepared to cover the meeting.

Dr. Weldon expressed his concern about the economic survival of Cordis Corporation which employs approximately 1,200 to 2,000 employees domestically and approximately 2,500 to 3,000 employees worldwide. He had met earlier this week with the Board of Directors and Dr. Weldon asked me if there were any bad feelings by FDA towards Dr. William P. Murphy, Chairman of the Board, or himself. I explained that there were no feelings of animosity toward any of the corporate officials, but that I was concerned about some of the decisions made in the past. I stated that Cordis had some serious problems which we have investigated and which we would have to react to as a Regulatory Agency but that no Agency decision had been reached. He explained that he was prepared to do something concerning a change of top corporate officials if it would help. My impression of what Dr. Weldon was trying to convey was simply that he and Dr. Murphy would resign if it would aid in the economic survival of Cordis Corporation and prevent litigation based on the findings of our current investigations.

Dr. Weldon stated that he has been advised by his SEC (Security Exchange Commission) Counsel to employ the services of a large unnamed law firm in Washington, D.C. who specializes in lobbying with the Department of Justice. He explained that the lobbying efforts would attempt to discourage the Department of Justice in filing a legal case recommended by FDA against Cordis Corporation and that he has seen where this approach has been successful in the past. Dr. Weldon mentioned a legal action recommended as a result of the Senate Committee on Aging as an example. Dr. Weldon stated that he did not agree with this approach and that he was raised as an Indiana "farm boy" and has always been honest and straightforward in his dealings and corporate decision making process. I replied that even if he employed the services of such a firm that I would hope it would not affect any Regulatory recommendation the Agency may make. He added that individuals have stated to him in the past that because of his honesty and straightforwardness, he would not be able to survive in the health related device industry. I added that there was no animosity against the corporate officials at Cordis Corporation. I explained that if we demonstrate that corporate officials are conspiring to circumvent our laws and regulations and presenting false information to us, our normal course of action is to recommend prosecution under Title 18. Dr. Weldon stated that I was in a position of power and could make decisions that could affect the fate of Cordis. I explained that I was not in a position of power, that I was only a supervisor, and only made recommendations which were subject to numerous levels of review.

Dr. Weldon stated that the corporate profits for Cordis Corporation will be approximately 50% of what had been projected for the fourth quarter and that this too would impact negatively on corporate operations.

He stated that he wanted to talk to me privately to ask if I could identify any one for him to express his concerns to. I stated that I thought such a meeting would be premature at this time, that as an Agency we had to evaluate our findings and that possibly in the future such a meeting could be arranged but that I could not commit to this one way or the other. I stated that I would express his concerns to Mr. Adam J. Trujillo, District Director. I explained that I recognized that any additional adverse publicity at this time would damage the Cordis image but that our efforts and investigations are aimed at the adequacy and control of the operations at Cordis over the past several years and that the Agency would have to evaluate these findings possibly on an ad hoc basis and decide on the proper Agency strategy. I explained that I considered our findings to be significant. I also explained that I was also limited as to what I could address in my discussions with him because he and I both had to operate within our own parameters which reflected on the information we could share with one another.

He reiterated that he had always been above board in his dealings and stated that he had shared adverse information with Medtronics on their polyurethane leads. He explained that Cordis had tested some of the Medtronics leads and that he had invited an individual from Medtronic (Bunker, I believe) to visit Cordis and review their adverse findings on the Medtronic pacemaker leads. He also stated that he had shared with a top corporate official at Medtronic (Larry Olson, I believe) a histogram on the early battery depletion problem in Cordis pacers. He stated that he was even thinking about sharing today's written June 22, 1984, response on the polypropylene protected pacers with Medtronic but that he had not made a final decision on whether or not he would do this. I asked if Medtronic had reciprocated in sharing their findings on any testing they had performed on Cordis products and he stated that they had not.

Dr. Weldon explained that a group of people who had tested the polyurethane leads at Medtronic had left ~~in~~ en mass and went to Intermedics, Inc., before the qualification testing was complete on the polyurethane leads. He said that he thought Medtronic marketed the polyurethane pacemaker leads before the testing was complete. He stated that he felt the polyurethane lead situation was more of a health hazard than the early battery depletion problem in pacers and that the Class I classification may have a major impact on the industry because Medtronic was not the only firm which used that particular type of polyurethane and that it was not isolated to one or two Medtronic models. He stated that Cordis distributed approximately 100 similar polyurethane pacemaker leads before they wised up. He added that Cordis had tested both Medtronic and Intermedics polyurethane leads but that the Medtronic leads always seemed to have the worst findings.

Dr. Weldon had explained during the meeting with all participants that he had recently appeared before staffers for the Senate Committee on Aging and had been asked to address FDA's role. This committee met about 1 to 2 years ago to investigate the extent of corruption in the industry and that the staffers he met with were trying to followup and update the prior investigation. I inquired if he met with the staffers before or after the article on Cordis in the (May 30, 1984) Wall Street Journal and he stated that he could not remember. Dr. Weldon stated that he spoke of his knowledge of some of the things going on within the medical device industry, i.e., providing automobiles to physicians and of his cooperation with GAO auditors and the FBI in explaining how various things are done.

Dr. Weldon stated that he explained to the Committee staffers that FDA had an impossible task before them and he mentioned specifically the new software developments in the industry. He stated that our people are not adequately trained and that even his people, engineers and computer types, had problems in keeping up and understanding the advancements within the software industry but that he believed human deaths will result in the future that will be directly associated with software. Dr. Weldon stated as a matter of course the subject of the ongoing investigation at Cordis and the time involved was touched upon but he did not elaborate upon this statement. Dr. Weldon also made a statement that he did not want to embarrass the Food and Drug Administration and he did not expand on this statement. My interpretation is that he was referring to the Intermedics, Inc., Freeport, Texas, situation which occurred in 1982 and before when they also had an early battery depletion problem that affected at least one model and a large number of pacers implanted as far back as 1979. FDA investigated on January 26-28 and February 1, 1982 and found that the firm had sent out several Product Updates but that FDA never classified the firm's action as a Notification, Recall, or market withdrawal. Cordis provided a copy of the Intermedics EIR to us on February 6, 1984, which was forwarded by Miami Resident Post to OMD, HFK-113. The projected life of the Intermedics pacer had decreased from 10 years to 2.9 years because of battery problems and I believe that more than one pacer model may have been involved.

Cordis has referred to the non-uniformity of the Agency's actions in the past in that we classified their problem as a Class I Recall which has had a significant impact on Cordis and basically did nothing to address the Intermedics problems. Cordis has also stated that FDA only spent approximately one week at Medtronics on the polyurethane problem and compared it with the time we have spent at Cordis.

I expressed my frustrations in trying to do everything possible to bring our investigation to a conclusion. I explained that I was going to expend the necessary resources to investigate the potential problems referred to us in the anonymous complaints until I was certain of their impact on the population which used the applicable Cordis products. I explained that one of the reasons for our prolonged investigation was that his Corporate Quality Assurance was not adequately staffed to allow our investigators to cover more than two problem areas at a time and that they had lost three people in Corporate Quality Assurance which had not been replaced. He stated that it was difficult to replace these positions with someone who is not adequately trained. I replied that this was true but that they could assist investigators with simple matters and more experienced people could handle the more complex issues. I stated that if someone had been assigned this past January, they would have possibly attained invaluable experience by now. He stated that he had an employee in January who he was thinking of assigning to Corporate Quality Assurance but because of the problems in Plant 7, he decided to assign the employee there.

James A. Casey
Supervisory Investigator
Miami Resident Post

dec'd/HFR-4200/Mr. Trujillo (Furr) 7/2/84
dec'd/HFR-42/ Mr. Kinslow 7/2/84
dec'd/HFC-1/Mr. Hile 7/2/84
dec'd/HFZ-2/Mr. Benson 7/2/84

THE COMMISSIONER OF SOCIAL SECURITY
BALTIMORE MARYLAND 21235

JUN 29 1984

Refer to:
SIB61

RECEIVED
JUL 12 1984
COMPLIAN[illegible] ORL-DO

Mr. Edward R. Atkins
Acting Director
Orlando District
Food and Drug Administration
P.O. Box 118
Orlando, Florida 32802

Dear Mr. Atkins:

This refers to your letter of June 19, 1984 concerning your desire to locate 354 people who have cardiac pacemakers manufactured by the Cordis Corporation.

The officials in our Office of Systems Requirements are being asked to review your request and to take appropriate action. You should hear from them as soon as possible.

Sincerely,

Martha A. McSteen

Martha A. McSteen
Acting Commissioner

July 10, 1984

Acting Director, Orlando District (HFR-4200)

84-374-481, Gamma Pacemaker

Cordis Corporation
10555 W. Flagler St.
Miami, FL 33172

Director, Office of Compliance,
Office of Medical Devices (HFZ-300)

REQUEST FOR AD HOC REVIEW COMMITTEE

The purpose of this document is to provide background and significant inspectional findings from recent Orlando District inspections of the Cordis Corporation, and to request the formation of an Ad Hoc Committee. The inspections were conducted to investigate the causes of the Class I recall of Gamma Series cardiac pacemakers because of early battery depletion, and to follow-up serious anonymous complaints regarding the firm's management, manufacturing procedures and products. Because of the serious nature of inspectional findings and potential for adverse consequences, Orlando District requests that an Ad Hoc Committee be established to evaluate inspectional findings and to formulate Agency strategy regarding possible legal action against the firm.

BACKGROUND

Cordis Corporation, Miami, FL was established in 1959 and has become a major manufacturer of medical devices for world-wide distribution. The company is principally involved in the development and manufacture of cardiac pacemakers (pacers), angiography catheters, neuroscience products, and accessories for these items. They currently manufacture approximately 15 models of pacers, including physiological models, approximately 15 types of pervenous and epicardial leads, and approximately 50 types of angiographic catheters. The firm employs approximately 3,000 individuals and had a 1983 net sales of $164,343,000.

On December 2, 1983, Cordis advised Orlando District of their decision to notify physicians of potential early battery depletion (EBD) in six (6) models of Gamma series pacers distributed between January 1980 and August 1983. The physician notification letter was subsequently issued on December 5, 1983. The firm's action was classified as a Class I recall (Z-064/067-4) by the Agency on May 13, 1984.

The inspection initiated on December 2, 1983, disclosed that in November 1979, the firm submitted a 510(k) premarket notification for Gamma series pacers that incorporated a hermetically sealed lithium/cupric sulfide battery. Each pacer contained one battery which in turn contained two hermetically sealed cells, also called gamma cells. The positive lead passes from the inside to the outside of the cell through a glass feedthrough which serves to insulate the positive lead from the cell container which acts as the negative terminal.

In June 1980, Cordis testing revealed corrosion and low resistance of the glass feedthrough. Corrosion of the glass feedthrough can create a bridge that permits an electrical short that triggers depletion of the available power. Usually, one cell is depleted and this causes the pacer to malfunction. In October 1980, Cordis modified manufacturing procedures to apply a polypropylene sleeve to the glass feedthrough. The polypropylene sleeve was replaced with a polyimide coating in March 1982 because it reportedly provided better protection and was easier to apply. The firm did not submit 510(k) notifications for the protection of the glass feedthrough until April 1984 after being advised to do so by OMD during a meeting on December 7, 1983.

ANONYMOUS COMPLAINTS

Between September 1983 and March 1984, the Agency received three (3) anonymous complaints regarding Cordis management, manufacturing procedures, and product problems.

(1) Internal Cordis memorandum dated September 21, 1983, subject "Special Audit - Gamma Battery Cell Depletion". This document described 134 premature Gamma battery depletions and included an internal audit of Cordis' manufacturing, testing and release of Gamma battery cells in use during 1980.

(2) On March 15, 1984, the Office of Medical Devices provided Orlando District with an anonymous complaint consisting of an undated letter, postmarked February 29, 1984, along with approximately 26 groups of documents. In summary, this complaint alleged that Cordis Corporation has no sense of moral responsibility or interest in patient safety, and that executive management constantly mandates that inferior products be produced without regard for quality or Federal Laws. It suggested that FDA investigate the firm's Material Review Record (MRR) system and the 190A series pacemakers which have a "deadly hidden flaw in them". This complaint was reportedly also sent to various members of the U.S. Senate.

(3) On March 26, 1984, the Chief, Bioresearch Monitoring Branch, OMD, (HFZ-341), provided Orlando District with an anonymous complaint postmarked February 28, 1984, which alleged that Cordis' Orthocor Antytachycardia pacer "is plagued with problems, and is very susceptive to false triggering by EMI which result in patient death." The

complaint further alleges corporate officials were "aware of the flaws" and "they have altered test data and changed reports to indicate the pacer works". This complaint concerns IDE Number G840004 for which OMD sent a deficiency letter on February 13, 1984.

INSPECTIONAL FINDINGS

Inspections at Cordis have been continuing since December 1983, to investigate problems associated with Gamma pacer EBD, a Headquarters assignment regarding pacemaker polyurethane leads, a recall of angiographic catheters because of leakage at the hub to catheter bond, the previously described anonymous complaints, and GMP's. We have utilized three (3) District Investigators and three Engineers from Houston Station and WEAC in our attempt to complete the investigations promptly. However, the firm has been unable to produce documents when requested and usually requires several days to do so. Even then, much of the information has been incomplete and required verification. These delays, plus the sheer volume of highly technical information and magnitude of problems encountered at the firm, account for the time involved. Five inspection reports dated December 3/April 21, April 4/May 1, April 11/27, April 16/June 5, and April 16/May 15, 1984, have been forwarded to the Office of Medical Devices for review and evaluation. Two additional inspection reports are in process and will be provided as soon as they are completed.

Significant problems have been identified in the following areas:

A. GMP Deficiencies

Inspections conducted have revealed the following major deficiencies:

1. Inadequate component specifications.
2. Inadequate testing of components.
3. Use of components that failed to meet specifications.
4. Use of waivers or temporary authorities to authorize component use when specifications were not met.
5. Failure to document and verify completion of each manufacturing step.
6. Failure to prepare and maintain a written record of each complaint and the review, evaluation, and investigation for each such complaint.

Most of these deficiencies relate to the battery manufacturing and pacer production in 1980, 1981, and 1982. Because of the scope of our investigation and the amount of time required, we have been unable to evaluate current GMP's. Information regarding the identified deficiencies may be obtained from the individual inspection reports.

B. Polypropylene Protected Feedthrough

The polypropylene design change covered by the pending 510(k) notification may not adequately prevent corrosion of the glass feedthrough or early battery depletion due to self-discharge. This design change initiated with cell lot number #4180, was used on several models of pacemakers produced between November 1980 and August 1982. Approximately 21,000 pacemakers were manufactured with gamma batteries which incorporated the polypropylene design change. Approximately 6,500 additional pacers have been implanted which incorporate Theta 1/4 Pi cells that also utilize polypropylene "protected" feedthroughs. These include Gemini (415) and Sequicor (233F) pacers.

Corporate management reportedly was not aware of a 200 cell test study conducted by their own personnel between 1980 and 1982 which should have impacted significantly on the firm's decision to notify physicians of the early battery depletion problem in Gamma series pacers. This study confirmed that EBD observed at accelerated temperatures could be extrapolated to predict EBD at body temperature. The test data were reportedly not evaluated until August 1983 which was approximately four months before the firm made the decision to notify physicians of the EBD problem. Other documents have been prepared by Cordis personnel which directed attention to testing results relating to EBD and the corrosion problem.

Following the change to the polypropylene sleeve protected feedthroughs in October 1980, Cordis distributed 6,260 pacers without glass feedthrough protection until the supply was depleted in October 1982. Likewise, the firm, even now, continues to distribute pacers with polypropylene protected cell feedthroughs, even though they have demonstrated that polyimide protection is more effective. We are concerned that these polypropylene protected cells may experience EBD after being implanted for four years even though they are marketed for 7 to 10 years. We submitted a memorandum dated June 27, 1984 to CDRH/Office of Compliance (HFZ-300), recommending evaluation of this situation.

C. Crosstalk Problem

The Cordis Sequicor and Gemini series of pacers are duel-chamber pacers, which sense and stimulate cardiac activity in either or both chambers of the heart. The firm has received complaints of "crosstalk" in the Gemini, Model 415A, pacer. The firm defines "crosstalk" as the interaction between the two channels of an automatic universal cardiac pacer (DDD) in which the sensing of one channel is affected by the output of the other channel. In this particular instance, the ventricle channel was affected by the atrial output channel.

Cordis manufactured approximately 1200 Gemini, Model 415 pacers which were implanted in a clinical study beginning in 1982 which had a dual anodal ring. The problem of "crosstalk" is associated with only 190 of these investigational pacers, which have been identified as being implanted with non-Cordis leads. The problem seems to have occurred in pacers where body fluid leaked into the neck of the pacer around a competitor's lead. Thus far, the firm has had 11 complaints of this phenomenon. The Premarket Approval letter for the Gemini pacers was issued in November 1983. We have been unable to confirm if Cordis submitted a request for additional implants under the IDE.

Cordis failed to notify FDA of any of the "crosstalk" complaints including one which resulted in an explant (415A-1561). Prior to our inspection of April 16-June 26, 1984, no investigation had been conducted by the firm to determine the exact reason for the explanted pacer to fail. Cordis chose to notify the clinical investigators of this potential problem by means of the annual progress report sent to clinical investigators rather than by direct notification of the investigators who are monitoring the 190 patients with the potential problem pacers.

The firm supposedly corrected the problem by removing the anodal rings. This correction allows for using Cordis' or a competitors lead and prevents leaking of body fluids into the neck of the pacer. There have been no complaints of "cross-talk" in the Sequicor pacers.

D. 510(k) Notifications

1. Cordis failed to submit premarket notifications [510(k)] for the polypropylene and polyimide design changes to insulate and protect the glass feedthrough in their hermetic lithium cells. Initially, Cordis manufactured these cells with unprotected feedthroughs to which they attributed the cause of the early battery depletion problem and which led to the December 5, 1983 notification letter. Cordis submitted a combined retrospective 510(k) notification on April 4, 1984, for the polypropylene and polyimide changes at the December 7, 1983 request of OMD and later an Equivalence Summary re 510(k) #K841414 dated June 5, 1984. This information is under review by the Center.

2. The firm continues to manufacture and distribute the Mini-Gamma (Pediatric) Model 340A pacer without submitting a 510(k). This pacer weighs considerably less that its closest Cordis 510(k) counterpart, is smaller in size, and incorporates smaller hermetic lithium/cupric sulfide batteries with the polypropylene "protected" glass feedthroughs. See ORL-DO memorandum to OMD/Office of Compliance (HFZ-300) dated May 8, 1984 for additional information.

3. Cordis has failed to submit a notification to the Agency of the changes initiated to correct the printed wire board used in the Lambda pacemakers #208, 217, 221, 232, 235, 236 and Theta 237. Other models of the Lambda, Theta, and Stanicor Q and R series are similar to the Lambda 190 pacer marketed in early 1976 and Cordis didnot submit 510(k) notifications.

E. Other Products causing Adverse Reactions

Cordis has not notified the Agency in a timely manner of potential health hazards associated with defective or failed devices:

1. Printed Wiring Board

The Lambda, Theta and Stanicor Q and R series pacers have experienced a combination of malfunctions including early battery depletion, reed switch, and printed wiring board failures. The printed wiring board failure appears to be the most serious and results in sudden failure. Cordis states that dioxolane vapor given off by the crimped D-cell lithium battery is absorbed by the printed wiring board. These boards may then expand, causing the unfilled plated through holes to crack; thereby, stopping the flow of electricity and producing a sudden "no output" failure. Thus far, 690 failures of explanted Lambda Model 190A pacers have been confirmed through the company's own laboratory testing. In September 1980, Cordis modified the manufacturing procedure to fill the open through holes with solder on all pacers manufactured. However, they continued to sell the uncorrected pacers in inventory through 1983. Approximately 18,769 of these pacers remain implanted.

The Theta series pacers have experienced malfunctions in their electronic circuitry, as well as printed wiring board failures. Each of these failure modes may result in sudden failure. Distribution of the uncorrected Theta series pacers continued after the correction was initiated on the assembly line and at least 3,566 remain implanted. The theoretical service life of the Theta series pacers ranges between 13 and 18 years.

In addition, the Stanicor Q and R pacers utilize the lithium crimped cells that are subject to printed wiring board problems. A total of 3,135 pacers involving 3 models and 11 types were distributed both domestically and foreign after the problem was identified and correction initiated in pacers being assembled. The firm has issued several "Technical Memoranda" and "Product Updates" regarding this situation and initially recommended physicians to monitor their patients and to explant if the rate output is decreased by 10% or >2 pulses per minute. In addition, Cordis failed to properly evaluate the failed wiring boards to determine why the thick board (0.031") fails and the thin board (0.018") does not. Seven pacers (208, 217, 221, 232, 235, 236, and 237) were subject to 510(k) notifications, but the Agency was not advised of these failure problems. We do not believe the firm has adequately notified the physicians or the Agency of the significance of the abrupt failure problem.

2. Polyurethane Leads

Cordis has used both Texin MD 85A polyurethane and Texin MD 85A polyurethane containing 30% barium sulfate in the manufacture of their pacemaker leads. Both types of materials have demonstrated degradation (cracks) in animal studies where the leads were implanted in rabbit muscle tissue. Cordis has distributed 235 cardiac leads (Models 322-745 and 322-769) and 195 spinal leads (Model 691-102) manufactured with the Texin-MD 85A polyurethane. In addition, the firm also distributed 177 cardiac leads manufactured with Texin MD 85A polyurethane containing 30% barium sulfate for an IDE study. Cordis has extremely poor accountability of the pacemaker leads used in the clinical trials which covered a period from June 1980 to January 19, 1981. The study concluded with only 64 of the 177 leads accounted for and no knowledge of the missing 113 leads. Orlando District submitted the EIR and a memorandum to CDRH/Division of Compliance Operations (HFZ-323), dated May 9, 1984 covering this matter.

3. Catheters

Cordis implemented an in-line inspection change for their balloon-tipped catheters following a complaint in which the catheter's tip came off in a patient. This inspection change resulted in the rejection rate increasing from 3% to 19%; however, the firm failed to inspect their inventory of balloon-tipped catheters that had previously been accepted using the old inspection procedure. These catheters continued to be sold.

F. Possible Obstruction

Several incidents have occurred that raise questions regarding management's intent to comply with the statute and regulations enforced by FDA:

1. A memo from John N. Pagones, Vice President, Corporate Product Assurance, addressing a task force assignment to investigate the battery depletion problem in Gamma cells and Gamma pacers was revised prior to being given to FDA to eliminate eight comments pertaining to specific areas to be investigated.

2. Failure to log, document, and evaluate complaints and possible lawsuits as adverse reactions.

3. Failure to make 510(k) submissions for significant changes in device design such as the polypropylene or polyimide protection added to the glass feedthrough of the Gamma cell.

4. Failure to provide complete information with 510(k) submissions on the Gamma pacers and polyurethane leads.

5. Failure to advise FDA within 10 days of adverse reactions relating to crosstalk in the Gemini pacers as well as other adverse reactions.

Cordis Responses

Cordis management has stated that decisions made on the design and marketing of the products initially, as well as the changes instituted afterward, were made with the current state-of-the-art technology. They maintain that hindsight should not be used in evaluation because the problems were not evident but developed over a period of time. They contend that the unprotected glass feedthrough problem constituted state-of-the-art technology that could not be prevented. Cordis management believes that the polypropylene and polyimide corrections have solved the feedthrough degradation problem. In general they maintain that the firms strives to comply with Agency regulations and GMP's.

Cordis has submitted three written responses during our investigation. On June 1, 1984, Cordis representative presented a written response dated May 31, 1984, to District personnel in Orlando. The response consisted of two volumes of documents, speaking to GMP's and other violations and their correction or disagreement with FDA-483 observations relating to the Gamma pacers. The second response dated June 2, 1984, was presented to Miami Resident Post personnel. This document contends that pacers containing cells with polypropylene protected glass feedthroughs are safe and effective. The third response to Inspectional Observation of April 6, 1984, May 15, 1984 and April 27, 1984 was received by the District on July 2, 1984 and is undergoing review. Copies of all responses have been provided to OMD.

Pending Decisions

Copies of the inspection reports and exhibits have been forwarded to the Office of Medical Devices as completed. In addition, ORL-DO has submitted the following documents to update or recommend action by the Office of Medical Devices.

1. On March 19, 1984, we submitted a memo updating our ongoing inspection of Cordis to the Office of Medical Devices, Division of Compliance and Regulatory Guidance Branch and the Associate

Commissioner for Regulatory Affairs, Enforcement Policy Staff. This memo called attention to the problems encountered during our inspection at that time.

2. On May 8, 1984, we submitted a request for premarket notification for the Multicor Mini-Gamma Model 340A to the OMD/Division of Compliance Operations (HFZ-320), because of the continued manufacture and distribution of this pacer with the polypropylene protection to the battery glass feedthrough. This pacer was not included in the Class I recall. The firm has not submitted a 510(k) notification in spite of several differences from the larger standard Gamma pacer. We have not been advised of OMB's decision.

3. On May 9, 1984, we submitted a memo to OMD/Division of Compliance Operations (HFZ-323), requesting review and evaluation of an inspection concerning polyurethane pacemaker leads. The inspection conducted March 15/April 6, 1984, revealed decisions by the firm to continue distribution of leads that had been released but were made of material that did not resist surface cracking. We have not been advised of OMB's decision.

4. On June 27, 1984, we submitted a memo to OMD/Division of Compliance (HFZ-300), requesting evaluation of our concerns that Gamma pacers containing batteries with polypropylene protected glass feedthroughs may fail due to early battery depletion (EBD). We also requested consideration be given to disapproving the pending 510(k) notification and advising the firm to cease marketing Gamma pacers containing batteries with polypropylene protected feedthroughs pending submission of further studies to demonstrate effectiveness. We have not been advised of OMD's decision.

Summary

Although our documentation to date does not identify any one individual to have acted with intent in efforts to manufacture and distribute adulterated and misbranded devices, the problems encountered combined with the decisions made to continue marketing Class III devices that later developed serious problems is indicative of severe deficiencies in the firm's operations and management. Since such forethought or intent is not necessary, we believe the firm's reliance on "state-of-the-art" as justification for these problems, without adequate qualification of design, to be unacceptable to preclude legal action.

Of interest is that Cordis was the target of an injunction filed by the Agency in 1975. A special Commissioner was appointed by the Court to hear the case and subsequently rendered an opinion that was adopted by the

Court. Although the Court denied our injunction, the findings of the Commissioner included 13 areas that required improvement to reach a status of "rigidly controlled." These areas included component specifications, controlling the use of waivers, and development of a larger role for product assurance management in Material Review Board procedures as well as others. Subsequent inspections revealed the firm to have made significant improvements in manufacturing procedures.

The firm continues to make decisions regarding the distribution of products which indicates that marketing and technical advances are more important than reliability. This is demonstrated by the firm's continued marketing of products with known defects after correction is initiated on the assembly line.

Recommendations

Because of the above findings, we recommend that an Ad Hoc Committee meet as soon as possible to assess the seriousness of our inspectional findings and to develop an Agency strategy to address the matters at Cordis.

Possible alternatives, or combinations of these options, appear to include the following:

1. Referral to the U. S. Attorney for a Grand Jury investigation.

2. Consideration of a Cite recommendation under Section 305.

3. Continuation of our inspections to include current GMP's and new products in production. Any delay in consideration of a prosecution will impact on any future case because of the statute of limitations that is closing on Cordis actions in 1979 and 1980.

4. Consideration of action under Section 518 of the Act to order refund or replacement to patients of one or more of the following:

   a. All Gamma pacers that contain batteries with unprotected feedthroughs.

   b. The 6,280 Gamma pacers containing batteries with unprotected feedthroughs that were distributed after November 1980, when polypropylene protection was added to cells used in the Gamma pacers.

   c. The Gamma pacers containing batteries with polypropylene protected feedthroughs.

5. Consideration under Section 515 of the Act to withdraw approval of the PMA for the Gemini and Sequicor pacers under (e)(1)(A), (e)(1)(B), and/or (e)(1)(C).

6. Consideration of non-approval of the pending 510(k) notification from Cordis on the use of polypropylene and polyimide protection to the battery glass feedthrough pending additional studies or testing to demonstrate safety and effectiveness.

Maurice D. Kinslow, Regional Director, Atlanta Region is aware of and concurs in this request.

Lamar H. Furr

cc: M. D. Kinslow, HFR-41
A. Levine, GCF-1
M. Shumate, HFC-20

bcc: HFR-4200/AJT Chron
HFR-4240/ERA
HFR-4250/CCR
HFR-4575/MIA - JAC
HFR-1380/Bruce Burnett

JACASEY/CCREYNOLDS/ERATKINS/LHFURR/aml 7/2/84
FINAL 7/10/84

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION	DISTRICT ADDRESS 7200 Lake Ellenor Drive, Ste 120 Orlando, FL 32809	
NAME OF INDIVIDUAL TO WHOM REPORT ISSUED TO: Harold (nmi) Hershenson	DATE OF INSPECTION 7/23,26,30,31;8/3,6,8/10,16/84	C. F. NUMBER 1016427
TITLE OF INDIVIDUAL Executive Vice President	TYPE ESTABLISHMENT INSPECTED (i.e. bakery, cannery) Medical Device Manufacturer	
FIRM NAME Cordis Corporation	NAME OF FIRM, BRANCH OR UNIT INSPECTED Same	
STREET ADDRESS 10555 W. Flagler St.	STREET ADDRESS OF PREMISES INSPECTED Same	
CITY AND STATE Miami, FL	CITY AND STATE Same	

DURING AN INSPECTION OF YOUR FIRM (I) · (WE) OBSERVED:

1. Between January 1, 1980 and November 28, 1983, the firm reworked/reprocessed a total of 254 Gamma and Theta weld/qual pacers, subjected to 115° C temperature during gas-analysis, without appropriate written procedures describing the criteria for "salvaging" or "replacing" batteries by production. The decision made during a meeting held by production sometime in 1980 to salvage the batteries of Gamma weld/qual sample pacers was not documented.

2. There are no written procedures concerning the disposition of pacers undergoing gas analysis at 115° C. This resulted in the subsequent shipment/implant of at least 55 Gamma and Theta weld/qual pacers with the batteries still in place and of approximately 55 (Gamma and Theta) weld/qual pacers with replaced batteries which had been subjected to 115° C temperatures for 7 to 24 hours during gas-analysis. (For example, Gamma pacers Models 337A S/Ns 3420, 7929, etc.; Sequicor pacer Models 233F S/N s 8770, 9549, etc.) No evaluation had been conducted to determine any adverse effects on pacers exposed to 115° C temperature prior to 12/83 after Cordis learned of a malfunction in a pacer that had been exposed to 115° C temperature and inadvertently released for sale.

3. The temperatures used during gas analysis of Theta (can type) weld/qual pacers was changed by the laboratory from 37° to 115° in March 1983, but production was not notified of this change. There is no written documentation authorizing this change. Of 29 affected pacers containg hermetically sealed batteries, four, with batteries that had not been replaced after undergoing gas analysis, were subsequently implanted.

Cordis Control of Discrepant Materials states that components, subassemblies or assemblies subjected to abnormal environmental stresses are discrepant and that these incidents with pertinent information relative to the abnormal conditions much be recorded on an MRR. This procedure has been in effect since at least 6/17/81.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Veronika J. Fabritzky	EMPLOYEE(S) NAME AND TITLE (Print or Type) VERONIKA J FABRITZKY INVESTIGATOR

FORM FDA 483 (12/78) PREVIOUS EDITION MAY BE USED. INSPECTIONAL OBSERVATIONS PAGE OF PAGES

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS
7200 Lake Ellenor Drive, Suite 120
Orlando, FL 32809

NAME OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Harold (nmi) Hershenson

DATE OF INSPECTION
7/23,26,30,31;8/3,6,
8/10,16/84

C. F. NUMBER
1016427

TITLE OF INDIVIDUAL
Executive Vice President

TYPE ESTABLISHMENT INSPECTED (i.e. bakery, cannery)
Medical Device Manufacturer

FIRM NAME
Cordis Corporation

NAME OF FIRM, BRANCH OR UNIT INSPECTED
Same

STREET ADDRESS
10555 W. Flagler St.

STREET ADDRESS OF PREMISES INSPECTED
Same

CITY AND STATE
Miami, FL

CITY AND STATE
Same

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

4. Lithium Hermetic Cell, specification 9501149 (paragraph 5.3.3 states that the highest temperature to which the cell may be exposed to is 54.5° C). The firm has deviated from this specification in that pacers subjected to 115° C for 7 to 24 hours during gas analysis have been shipped and implanted.

5. The firm's followup investigation to determine disposition of all pacers (Gamma and Theta) subjected to 115° C was incomplete for the following reasons observed:

1. The firm's Attachment III attached to memorandum dated 2/13/84 provided on 7/30/84 fails to identify the disposition of all pacers, specifically those which had been shipped either as a consignment pacer or for export (with or without replaced batteries) which may also have been implanted, but not registered. On the second, partial summary based on reportedly sales data furnished on 8/10/84, at least 5 additional Gamma pacers without replaced batteries and 30 Gamma pacers with replaced batteries were identified to have been shipped. The five pacers were not listed on the 7/27/84 memorandum (also furnished on 7/30/84) among the pacers implanted with unreplaced batteries shipped/implanted. (337A-14583, 15343; 1708; and 334A-8729 and 9837).

2. There was no followup to determine if a possibility of pacer failure existed involving two patients who died. These patients were implanted with Gamma pacers subjected to 115° C and shipped/implanted with the original, unreplaced batteries (334A-3871 and 337A-7929).

6. The firm's December 19, 1983, followup investigation to the malfunctioning, explanted field returned pacer 233F-09549 implicated that the oven used for pacer conditioning prior to gas-analysis had "run away tendencies" and could of had mal-functioned causing the Pellon separators to melt. However, a temperature profile of the Blue M oven (Cordis #2707) was not performed until 7/20/84.

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Veronika J Fabritzky

EMPLOYEE(S) NAME AND TITLE (Print or Type)
VERONIKA J. FABRITZKY
INVESTIGATOR

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NAME OF INDIVIDUAL TO WHOM REPORT ISSUED TO: Harold (nmi) Hershenson	DATE OF INSPECTION 7/23,26,30,31;8/3,6, 8/10,16/84 — C. F. NUMBER 1016427
TITLE OF INDIVIDUAL Executive Vice President	TYPE ESTABLISHMENT INSPECTED (i.e. bakery, cannery) Medical Device Manufacturer
FIRM NAME Cordis Corporation	NAME OF FIRM, BRANCH OR UNIT INSPECTED Same
STREET ADDRESS 10555 W. Flagler St.	STREET ADDRESS OF PREMISES INSPECTED Same.
CITY AND STATE Miami, FL	CITY AND STATE Same

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

7. The firm has no written procedures covering "pacer conditioning" prior to gas-analysis describing oven temperatures, length of time of exposure, oven used and listing appropriate gas analysis test procedure.

8. The "Blue M" oven (Cordis #2707) used for the gas analysis of all Gamma and Theta weld/qual pacer samples was not calibrated between 1/29/81 and 7/15/83, even though the firm's own calibration record indicates a six months recalibration schedule. There are no records which document the temperature of the oven during this period. According to the Cordis calibration record for the "Blue M" oven (S/N 2707), the 7/15/83 calibration was done at 75° C only.

9. There is no written procedure for calibrating the "Blue M" ovens.

10. The name and Cordis identification number for the Pyrotest instrument used to calibrate the Blue M (Cordis #2707) oven was never entered on the appropriate Cordis Calibration/Preventive Maintenance Record. In addition, the associated calibration record dated 1/29/81 report #1030-02 also fails to show the Cordis ID number for the Pyro test instrument.

11. The device history record (travel document) for pacer Model 334A-1840 fails to show the step that the unit was taken as a random qual sample for gas-analysis. The unit was subjected to gas analysis on 5/21/80 according to available laboratory records.

12. There is no written procedure for criteria/specifications of when a pacer becomes a charitable donation as opposed to scrap. At least 19 pacers identified with parameters to be out of specifications (such as programmed rate, Haversine sensitivity, etc.) were donated between January 1982 and June 1984. (For example: Omni-Stanicor pacer 237A 6647 at 7 (high) in a 6.5-7.5 mA); Multicor Gamma pacer 337A-11240 at 5.5 mV positive sensitivity the ready was 6.2 mV (Cordis limits 5.5 ± 0.5 mV); etc.).

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NAME OF INDIVIDUAL TO WHOM REPORT ISSUED TO: Harold (nmi) Hershenson	DATE OF INSPECTION 7/23,26,30,31;8/2, 8/6,10,16/84 — C. F. NUMBER 1016427
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CITY AND STATE Miami, FL	CITY AND STATE Same

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

13. The firm has not notified FDA through PMA supplement regarding pacers identified for donation for charitable distribution which do not meet Cordis specifications. ~~For~~ example, Sequicor II Model 233F - 10490 currently ready for donation.

14. As of 8/16/84, the firm was unable to locate Multicor Gamma pacer 337A 4823 which was found out of specification for programmed rate and subsequently became designated as a "Chaffty Pacer".

15. For Omni Stanicor Gamma pacer 334A-9837 the device history record (traveler document) didn't reflect if an MRR had been written for gas analysis.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Veronika J. Fabritzky	EMPLOYEE(S) NAME AND TITLE (Print or Type) VERONIKA J FABRITZKY INVESTIGATOR

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PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

Recd. from Smith 9/28/84
This is an abridged version Don has a complete copy.

TO : Division of Compliance Operations
Center for Devices and Radiological Health

DATE: August 23, 1984

FROM : Supervisory Investigator, HFR-4575
Miami Resident Post

Mfr: Cordis Corporation
10555 W. Flagler St.
Miami, FL 33152

SUBJECT: Issues Identified by Ad Hoc Committee for Health Hazard Evaluation

The Ad Hoc Committee met on August 9, 1984, in Rockville, Maryland, and identified the below listed ten (10) areas/products for referral to the Office of Medical Devices' Health Hazard Committee for health hazard evaluation and possible action under Section 518(a). To assist in this evaluation and location of documents, the indicated attachments have been prepared.

1. Lambda and Theta pacers reference "printed wiring board" failures and others (Stanicor Q and Stanicor R) — SJT. ATTACHMENTS A, 2 pages, and B, 2 pages.

2. 115° C pacers including those with original, as well as replaced battery cells — VJF/VS. ATTACHMENT C, 6 pages.

3. 340A "Mini Gamma" pacers — VS. ATTACHMENT D, 1 page.

4. Programmer/software assessment — SJT. ATTACHMENT E, 1 page.

5. 415A "Crosstalk" problem — VS. ATTACHMENT F, 1 page.

6. Polyurethane lead degradation problem — SJT. ATTACHMENT G, 4 pages.

7. Balloon tipped catheter, 3 to 19% rejection rate — SJT. ATTACHMENT H, 1 page.

8. Adequacy of [redacted] feedthrough change and all models containing the [redacted] "protection" — VS. ATTACHMENT I, 1 page.

9. Orthocor II export, number of pacers approved by FDA for exportation and number actually shipped — SJT. ATTACHMENT J, 8 pages.

Buy U.S. Savings Bonds Regularly on the Payroll Savings Plan

1C. Orthocor I IDE — SJT. An inspection may be needed. A total of 90 (6 domestic and 24 foreign) Orthocor pacers have reportedly been implanted in 87 patients which includes three replacement pacers, due to overdrive problems and loss of sensing. A total of 7 complaints/adverse reactions have been received thus far. The final report covering the Orthocor I reportedly will be provided to FDA on September 7, 1984.

Separate memoranda covering the charity pacers and product updates are submitted as Attachments K dated August 20, 1984 (3 pages) and L dated August 23, 1984 (62 pages).

Please do not hesitate to contact me if clarification or additional information is required.

James A. Casey
James A. Casey

cc: HFZ-300 w/attach.
HFZ-450 w/attach.
HFR-4240 w/attach.
HFR-4575/JAC w/attach.
HFK-200/Dr [illegible] w/attach

ATTACHMENT A
(2 pages)

LAMBDA AND THETA PACERS - PRINTED WIRING BOARD

PRODUCT: Pacemakers - Lambda Models 1887B; 190A; 190E; 208; 215; 235; 236; Theta Models 221A; 221B; Stanicor Q-238B7; Stanicor R-241.

PROBLEM: The problem is that the plated through holes in the printed wiring board will separate or crack near the annular ring when the printed wiring board absorbs [redacted] vapor from the crimped D cell battery. The pacer will go to a no output mode suddenly. (Pages 14 and 16). The number of failures by model number are:

Model	# of Failures	Model	# of Failures
188B7	2	208A	1
190A	690	215A	1
190E	66	221A	42
		221B	7

Reference: Page 16, 17, 18, 19 and FD 483, #1.

Pacers subject to same failure mode which had not had any failures are 241, 235, 236, 238B7. (Ref. p. 17).

COMPLAINTS: There were four complaints in the firm's hazard file. Three were on 190A pacers and one was on a 190E pacer. Two of the patients had a cardiac arrest, one patient suffered a concussion after fainting, and one patient had a heart rate of 40 in the emergency room. (Ref. FD 483, #3 and pages 27 and 28).

HAZARD: The identified hazard is that the failed pacer may have been monitored only a few days prior to it failing. The pacer will suddenly stop when the plated through hole fails. This is very hazardous to "pacer dependent patients".

The firm has failed to properly notify the physicians concerning the problem. In product updates the firm has failed to specifically state that the printed wiring boards suddenly and without warning go to a no output mode. Also the firm has not listed all models subject to printed wiring board failures on product updates. (Ref. FD 483, #3 and 6, and pages 7 to 11).

ATTACHMENT A

LAMBDA AND THETA PACERS - PRINTED WIRING BOARD - Page 2

There are a total of 22,335 pacemakers (Models 190A, 190E, 221A7 and 221B7) reported as still implanted in the United States which are subject to this failure mode. The models subject to this failure mode and the amount the firm reports as still implanted are (Ref. page 20 and Exhibits 28 and 38):

Models	Total Implants	Reported Still Implanted	
188B7	1,107	1,072	
190A	21,845	17,371	
190E	1,789	1,398	
208	404	309	
215	121	100	
221A7	1,380	1,233	
221B7	2,471	2,333	
235A	186	160	
235B	106	102	
236A7	144	137	
238B7	314	298	
241A/B	369	349	24,862 Total

A July 6, 1984, investigation of Cardiovascular Surgery Associates, P.C., St. Thomas Medical Building, Suite 501, 4230 Harding Road, Nashville, TN 37205 (615) 385-4781 revealed that 18 patients had 190A pacemakers fail due to discrepant printed wiring boards. Reportedly, the firm is monitoring approximately 200 patients and the 18 failures represent a 9% failure rate. Also a physician in the group stated that some of the Model 190A pacers had an unpredicted output failure without first exhibiting an end-of-life rate drop indicator. Cordis letters to the physicians as recent as March 29, 1984, state "This appears to be a random malfunction".

REFERENCES:

1. EIR 4/16-5/15/84. FD 483 Observation #12, pages 5 & 6, pages 31-33, pages 37 and 40.

2. EIR 4/16-6/5/84. FD 483 Observations #1-6, & 8. This EIR deals almost exclusively with this plated through hole/printed wiring board problem. The pages, exhibits and FD 483 items referenced in this memo refer to this report.

3. EIR 6/20-8/10/84, Exhibit #150, the number of open plated through holes per printed wiring board.

Samples: DOC 84-374-546 - 190A Lambda Pacemaker.
DOC 84-374-547 - 221B7 Theta Pacemaker.

Stephen J. Tunks
Investigator, 171
Miami Resident Post

ATTACHMENT B

(2 pages)

LAMBDA AND THETA PACERS - EBD (EARLY BATTERY DEPLETION) FAILURES

PRODUCT: Lambda pacers with batteries manufactured prior to 4/5/78, the date the immediate burn-in of batteries was implemented. Reference: page 29-31, Exhibit #71.

The pacemakers involved are:

	Model	First Date of Manufacture
Lambda	188A7 and B7	4/4/77
	190A	2/10/76
	190E	7/29/76
	206A & B	12/15/76
Theta	221A7	10/7/77
	217	3/28/78

PROBLEM: Pacers manufactured with batteries not having immediate burn-in had failures which averaged 37.8 months. The failure mode is early battery depletion. The firm has distributed Technical Memorandum 30A, dated 9/22/80, which requests physicians explant if a rate decrease of 2 or more pulses per minute is detected. (Reference: Exhibit #5). Also the firm recommends to monitor the pacers once monthly by telephone or four times in 6 months clinically.

COMPLAINTS: The 190A had 2.76% of the implants fail and 190E had 2.13% of the implants fail. (Reference: Exhibit #37). The mean failure time is 37.8 months. There are a total number of failures per model number as follows: 188A7 - 154; 188B7 - 1; 190A - 647; 190E - 41; 190F - 5; 206A - 44; and 208A - 1. (Reference: Exhibit #74).

HAZARDS: Pacer dependent patients may suffer if the battery depletes prior to the pacer being replaced. In 1984 there were only 10 returns of pacers for early battery depletion that did not have immediate burn-in (Reference: p. 31); however, the estimated life of the pacers (Reference: p. 21) are:

Model	Life
188A7 & B7	12 years
190A	8-12 years
190E	8-12 years
206A	11-17 years
221A7	18 years
217	14.8 - 26.4 years

Also, there were very few pacemakers made prior to 4/15/78 for models 221A7 and 217 and those models do not have any EBD problems reported. No product updates on Theta pacers reference EBD.

ATTACHMENT B

LAMBDA AND THETA PACERS - EBD (EARLY BATTERY DEPLETION) FAILURES - Page 2

Only Technical Memorandum #30A issued on 9/22/80 requested increased monitoring and provided replacement guidelines. Product Updates issued on Lambda pacers since then did not contain the increased monitoring and replacement guidelines.

REFERENCES:

EIR 4/16-6/5/84 - pages 29 to 31.

Stephen J. Tunks
Investigator, 171
Miami Resident Post

ATTACHMENT C
(6 pages)

PACERS SUBJECTED TO GAS ANALYSIS AT 115° C.

PRODUCT: Gamma (334A, 333B7, 337A, 336A, 333D7, 402B), Sequicor (233F, 233G), Gemini (415A), Omni Stanicor (217A) and Stanicor (221B) pacemakers.

PROBLEM: Initially the firm reported that a total of 254 pacers, as identified by the firm during EI of 7/23, 26, 30, 31; 8/3, 6, 10, 16/84, as having undergone gas analysis at 115° C. The firm initially supplied information that indicated 147 pacers had not been implanted and that 107 pacers had been implanted. A total of 52 of the 107 pacers were reportedly implanted with the same battery cells which underwent gas analysis. The remaining 55 pacers were reported as being reworked by replacing the battery cells with new battery cells which had not been subjected to the high temperatures reached during the gas analysis. The firm has extremely poor accountability of the actual disposition the of 147 pacemakers they reported as not being implanted and which reportedly were scraped, salvaged, used as demos, used in life tests, void or computer indicated as "no match". Later the firm's investigation disclosed that approximately 275 pacers were subject to gas analysis; not 254 as initially reported.

COMPLAINTS: Firm has received 5 explanted pacers which were distributed and implanted after being subjected to gas analysis. The firm's failure analysis attribute failures to early battery depletion (EBD). In one instance, EBD was due to the melting of the [redacted] separators in both cells. A second return also with original batteries incorporating unprotected feedthroughs (337A-17592) failed due to early battery depletion. The remaining three malfunctioning/explanted units were distributed after the batteries were replaced but showed similar EBD diagnosis without any evidence of [redacted] melting. These five failures included three separate pacer models (233F, 337A, and 334A).

A random check requested by the FDA Investigator revealed that at least 36 additional pacers had been shipped or identified for shipment by Cordis. In addition, Cordis retrieved a total of four (3 model 233F and 1 model 415A) pacers for in-house testing which had been shipped (3) or located in finish goods inventory (1). Based on the inaccurate accountability initially reported by Cordis, FDA requested that a complete accountability be performed and the firm refused. Therefore, we are continuing our efforts to identify the total number of pacers subject to the high temperature gas analysis (115° C and above), the total number implanted and 100 percent accountability of the remaining units. This request was made again via telephone to John Pagones, Vice President, Corporate Quality Assurance on August 22, 1984.

ATTACHMENT C

HAZARD: Firm claims that no hazard is associated with the pacer components that were exposed to 115° C (or above) gas analysis for seven to twenty four hours. The firm did not routinely record the length of time the units were exposed to 115° C temperatures during gas-analysis; therefore, the actual length of time the pacers were subjected to the elevated temperatures cannot be documented. New procedures now call for scrapping everything, but the hybrids.

The firm had no written procedures to cover the various reworking or salvaging of the gas analysis pacers.

The inspectional report covering the gas analysis problem is being dictated and will be forwarded as soon as it is typed. Attached is a copy of the List of Observations issued during this inspection.

Veronika J. Fabritzky

Veronika J. Fabritzky
Investigator
Miami Resident Post

ATTACHMENT C

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION	DISTRICT ADDRESS 7200 Lake Ellenor Drive, Ste 120 Orlando, FL 32809

NAME OF INDIVIDUAL TO WHOM REPORT ISSUED TO: Harold (nmi) Hershenson	DATE OF INSPECTION 7/23,26,30,31;8/3,6, 8/10,16/84	C. F. NUMBER 1016427
TITLE OF INDIVIDUAL Executive Vice President	TYPE ESTABLISHMENT INSPECTED (i.e. bakery, cannery) Medical Device Manufacturer	
FIRM NAME Cordis Corporation	NAME OF FIRM, BRANCH OR UNIT INSPECTED Same	
STREET ADDRESS 10555 W. Flagler St.	STREET ADDRESS OF PREMISES INSPECTED Same	
CITY AND STATE Miami, FL	CITY AND STATE Same	

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

1. Between January 1, 1980 and November 28, 1983, the firm reworked/reprocessed a total of 254 Gamma and Theta weld/qual pacers, subjected to 115° C temperature during gas-analysis, without appropriate written procedures describing the criteria for "salvaging" or "replacing" batteries by production. The decision made during a meeting held by production sometime in 1980 to salvage the batteries of Gamma weld/qual sample pacers was not documented.

2. There are no written procedures concerning the disposition of pacers undergoing gas analysis at 115° C. This resulted in the subsequent shipment/implant of at least 55 Gamma and Theta weld/qual pacers with the batteries still in place and of approximately 55 (Gamma and Theta) weld/qual pacers with replaced batteries which had been subjected to 115° C temperatures for 7 to 24 hours during gas-analysis. (For example, Gamma pacers Models 337A S/Ns3420, 7929, etc.; Sequicor pacer Models 233F S/N s 8770, 9549, etc.) No evaluation had been conducted to determine any adverse effects on pacers exposed to 115° C temperature prior to 12/83 after Cordis learned of a malfunction in a pacer that had been exposed to 115° C temperature and inadvertently released for sale.

3. The temperatures used during gas analysis of Theta (can type) weld/qual pacers was changed by the laboratory from 37° to 115° in March 1983, but production was not notified of this change. There is no written documentation authorizing this change. Of 29 affected pacers containg hermetically sealed batteries, four, with batteries that had not been replaced after undergoing gas analysis, were subsequently implanted.

Cordis Control of Discrepant Materials states that components, subassemblies or assemblies subjected to abnormal environmental stresses are discrepant and that these incidents with pertinent information relative to the abnormal conditions much be recorded on an MRR. This procedure has been in effect since at least 6/17/81.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Veronika J Fabritzky	EMPLOYEE(S) NAME AND TITLE (Print or Type) VERONIKA J FABRITZKY INVESTIGATOR

FORM FDA 483 (12/78) PREVIOUS EDITION MAY BE USED. INSPECTIONAL OBSERVATIONS PAGE OF PAGES

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION	DISTRICT ADDRESS 7200 Lake Ellenor Drive, Suite 120 Orlando, FL 32809	
NAME OF INDIVIDUAL TO WHOM REPORT ISSUED TO: Harold (nmi) Hershenson	DATE OF INSPECTION 7/23,26,30,31;8/3,6, 8/10,16/84	C. F. NUMBER 1016427
TITLE OF INDIVIDUAL Executive Vice President	TYPE ESTABLISHMENT INSPECTED Medical Device Manufacturer	
FIRM NAME Cordis Corporation	NAME OF FIRM, BRANCH OR UNIT INSPECTED Same	
STREET ADDRESS 10555 W. Flagler St.	STREET ADDRESS OF PREMISES INSPECTED Same	
CITY AND STATE Miami, FL	CITY AND STATE Same	

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

4. Lithium Hermetic Cell, specification 9501149 (paragraph 5.3.3 states that the highest temperature to which the cell may be exposed to is 54.5° C). The firm has deviated from this specification in that pacers subjected to 115° C for 7 to 24 hours during [redacted] have been shipped and implanted.

5. The firm's followup investigation to determine disposition of all pacers (Gamma and Theta) subjected to 115° C was incomplete for the following reasons observed:

   1. The firm's Attachment III attached to memorandum dated 2/13/84 provided on 7/30/84 fails to identify the disposition of all pacers, specifically those which had been shipped either as a consignment pacer or for export (with or without replaced batteries) which may also have been implanted, but not registered. On the second, partial summary based on reportedly sales data furnished on 8/10/84, at least 5 additional Gamma pacers without replaced batteries and 30 Gamma pacers with replaced batteries were identified to have been shipped. The five pacers were not listed on the 7/27/84 memorandum (also furnished on 7/30/84) among the pacers implanted with unreplaced batteries shipped/implanted. (337A-14583, 15343: 1708; and 334A-8729 and 9837).

   2. There was no followup to determine if a possibility of pacer failure existed involving two patients who died. These patients were implanted with Gamma pacers subjected to 115° C and shipped/implanted with the original, unreplaced batteries (334A-3871 and 337A-7929).

6. The firm's December 19, 1983, followup investigation to the malfunctioning, explanted field returned pacer 237-09549 implicated that the oven used for pacer conditioning prior to [redacted] had "run away tendencies" and could of hed mal-functioned causing the Pellon separators to melt. However, a temperature profile of the Blue M oven (Cordis #2707) was not performed until 7/20/84.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Veronika / Fabritzky	EMPLOYEE(S) NAME AND TITLE (Print or Type) VERONIKA J FABRITZKY INVESTIGATOR

ATTACHMENT C

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS
7200 Lake Ellenor Drive, Suite 120
Orlando, FL 32809

NAME OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Harold (nmi) Hershenson

DATE OF INSPECTION
7/23,26,30,31;8/3,6,8/10,16/84

C. F. NUMBER
1016427

TITLE OF INDIVIDUAL
Executive Vice President

TYPE ESTABLISHMENT INSPECTED
Medical Device Manufacturer

FIRM NAME
Cordis Corporation

NAME OF FIRM, BRANCH OR UNIT INSPECTED
Same

STREET ADDRESS
10555 W. Flagler St.

STREET ADDRESS OF PREMISES INSPECTED
Same

CITY AND STATE
Miami, FL

CITY AND STATE
Same

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

7. The firm has no written procedures covering "pacer conditioning" prior to [redacted] describing oven temperatures, length of time of exposure, oven used and listing appropriate [redacted] test procedure.

8. The "Blue M" oven (Cordis #2707) used for the [redacted] of all Gamma and Theta weld/qual pacer samples was not calibrated between 1/29/81 and 7/15/83, even though the firm's own calibration record indicates a six months recalibration schedule. There are no records which document the temperature of the oven during this period. According to the Cordis calibration record for the "Blue M" oven (S/N 2707), the 7/15/83 calibration was done at 75° C only.

9. There is no written procedure for calibrating the "Blue M" ovens.

10. The name and Cordis identification number for the Pyrotest instrument used to calibrate the Blue M (Cordis #2707) oven was never entered on the appropriate Cordis Calibration/Preventive Maintenance Record. In addition, the associated calibration record dated 1/29/81 report #1030-02 also fails to show the Cordis ID number for the Pyro test instrument.

11. The device history record (travel document) for pacer Model 334A-1840 fails to show the step that the unit was taken as a random qual sample for gas-analysis. The unit was subjected to gas analysis on 5/21/80 according to available laboratory records.

12. There is no written procedure for criteria/specifications of when a pacer becomes a charitable donation as opposed to scrap. At least 19 pacers identified with parameters to be out of specifications (such as programmed rate, Haversine sensitivity, etc.) were donated between January 1982 and June 1984. (For example: Omni-Stanicor pacer 237A 6647 at 7 (high) in a 6.5-7.5 mA); Multicor Gamma pacer 337A-11240 at 5.5 mV positive sensitivity the ready was 6.2 mV (Cordis limits 5.5 ± 0.5 mV); etc.).

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE

EMPLOYEE(S) NAME AND TITLE (Print or Type)
VERONICA J. [illegible]
INVESTIGATOR

FORM FDA 483 (12/78) PREVIOUS EDITION MAY BE USED. INSPECTIONAL OBSERVATIONS PAGE OF PAGES

FOOD AND DRUG ADMINISTRATION	Orlando, FL 32809	
NAME OF INDIVIDUAL TO WHOM REPORT ISSUED TO: Harold (nmi) Hershenson	DATE OF INSPECTION 7/23,26,30,31;8/2, 8/6,10,16/84	C. F. NUMBER 1016427
TITLE OF INDIVIDUAL Executive Vice President	TYPE ESTABLISHMENT INSPECTED Medical Device Manufacturer	
FIRM NAME Cordis Corporation	NAME OF FIRM, BRANCH OR UNIT INSPECTED Same	
STREET ADDRESS 10555 W. Flagler St.	STREET ADDRESS OF PREMISES INSPECTED Same	
CITY AND STATE Miami, FL	CITY AND STATE Same	

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

13. The firm has not notified FDA through PMA supplement regarding pacers identified for donation for charitable distribution which do not meet Cordis specifications. For example, Sequicor-II Model 233F - 10490 currently ready for donation.

14. As of 8/16/84, the firm was unable to locate Multicor Gamma pacer 337A 4823 which was found out of specification for programmed rate and subsequently became designated as a "Charity Pacer".

15. For Omni Stanicor Gamma pacer 334A-9837 the device history record (traveler document) did not reflect if an MRR had been written for gas analysis.

16. There were 27 PSRs received by the Product Service Department for which additional information relative to product failure and patient hazard had been received by the Cordis legal department that had not been documented in respective PSRs as of June, 1984. and therefore this information was not accessable for FDA review.
In addition there were five cases involving 4 instances of xxxxxx hazard or potential hazard and one instance of patient death received by Cordis legal department for which PSRs were not completed until this inspection.

17. Validation item re gas analysis pacers

ATTACHMENT D
(1 page)

STATUS OF MINI-GAMMA MODEL 340A PACERS

PRODUCT: Multicor "Mini-Gamma" Model 340A pacemaker.

PROBLEM: Firm began marketing product without submitting 510(k) Notification. Firm believes this pacer is substantially equivalent to other Multicor pacers subject of 510(k) Notifications. Refer to memorandum dated May 8, 1984, to HFZ-300 which discusses this matter in detail. Pages 18 and 19 of the 4/4-5/15/84 EIR discuss the Model 340A pacer. Sample DOC 84-374-485 was collected to document differences between the Model 340A pacer and other similar 510(k) pacers. Approximately 800 Model 340A pacers are currently implanted.

COMPLAINTS: All complaints concerning Model 340A have involved early battery depletion in pacers incorporating cells that do not have feedthrough protection. These units were included with the Gamma pacer recall initiated on 12/5/83. No complaints have been received involving pacers that incorporate cells that have [redacted] protected feedthroughs. The firm continues to manufacture and distribute the 340A pacer incorporating cells with [redacted] protected feedthroughs.

HAZARD: The equivalence of this pacer has not been demonstrated by the firm since a 510(k) was not submitted prior to manufacture and distribution. The pacer is marketed primarily for use in pediatric patients.

Victor Spanioli
Investigator
Miami Resident Post

ATTACHMENT E

(1 page)

PROGRAMMER/SOFTWARE ASSESSMENT

PRODUCT: 255A III and 256 IAP Programmers.

PROBLEM: The instructions for software EPROM rev 3004 are included in Instructions for Use manual for 233F and 415A pacemakers. The instructions state that if the "stat set" button is pushed, the backup mode will go off and the pacemaker will pace at 70 bpm. In actuality, the backup mode does not go off and the pacemaker paces at 52-1/2 bpm. Rev. 3005 software corrects this problem; however, there are still 217/255A III programmers in the field which have 3004 Rev. software EPROMS. Only by use of an ECG can a physician determine if the patient is in backup mode.

COMPLAINTS: There have been no complaints, injuries, or deaths reported.

HAZARD: Not only does the pacer/programmer software problem pertain to stat set, the firm has many different revisions of software EPROMS in 255A III programmers in the field (page 5). The EPROM Rev level and amount are: 3002 - 114; 3003 - 1; 3004 - 217; 3005 - 1856; 3006 - 56.

Corrected manuals have been distributed with subsequent orders of 233F pacers and 415A pacers concerning the 3004 Rev EPROM vs. the 3005 Rev. EPROM. Assuming that each physician noticed the changed instructions, there were 55/233F and 1/415A pacers distributed to consignees which did not have subsequent shipments. Also, the manual explains an alternate method to get the pacer out of backup mode without using the "stat set" button.

The health hazard involved is that incorrect instructions were distributed with 721/233F pacers and 41/415A pacers. The pacers may be unnecessarily replaced if the pacer went into backup mode at 52-1/2 bpm.

REFERENCES:

EIR 5/31-6/20/84. This entire report and the FD 483 is dedicated to this problem.

Stephen J. Tunks
Investigator, 171
Miami Resident Post

ATTACHMENT F
(1 page)

"CROSSTALK" PHENOMENON IN GEMINI 415A PACERS

PRODUCT: Gemini 415A Pacemaker.

PROBLEM: Certain Gemini pacers having two anodal rings can manifest "crosstalk" whereby the atrial channel output may inhibit ventricular output or, in one case, stimulate the ventricles. The firm, reportedly, manufactured 1200 pacers with two anodal rings. On 2/28/83 the firm eliminated the atrial channel anodal ring as it was no longer needed since FDA required additional data before approving the IDE with respect to the indication of two lead pacing of one heart chamber. The firm elected to remove this indication from their IDE protocol and labeling. The firm has identified 190 units that may have been susceptible to this phenomenon as they have two anodal rings and use competitors leads. Pages 30, 31, 33, and 34 of the 4/16-6/26/84 EIR discuss the crosstalk problem.

The Gemini 1983 IDE annual progress report was reportedly submitted to OMD on or about May 26, 1983; however, this report does not reference or discuss any of the "crosstalk" complaints received prior to this date with the exception of that case attributed to an atrial lead displacement (415A-1115). Exhibit C1 in the 4/16-6/26/84 EIR lists four pacers (415A-1561, 415A-1934, 415A-1533, and 415A-1751) that manifested "crosstalk" prior to May 26, 1983, that were not reported to FDA in the 1983 progress report. This exhibit, on page 3, also states that the atrial lead displacement "crosstalk" complaint was reported in the 1983 IDE progress report and that the remaining 11 crosstalk complaints would be reported in the next progress report due in June 1984. The firm did not have an explanation as to why the above four "crosstalk" complaints were not included in the 1983 progress report.

COMPLAINT: Twelve complaints have been received by Cordis (see Exhibit C1 in the 4/16-6/26/84 EIR). One patient was reported to have experienced syncope as a result of the "crosstalk". This problem is discussed in the Model 415A Final IDE report dated June 1984, which was to be sent to all investigators who implanted units with two anodal rings. A copy of this report was sent to OMD by Cordis on June 25, 1984.

HAZARD: It is unknown if any hazardous condition remains at this time with respect to those patients having units with two anodal rings and competitors leads since "crosstalk" normally is manifested early after implant (all cases have been diagnosed less than 12 months after pacer implant). Cordis believes that any leakage that might occur around competitor's leads into the pacer neck eventually ceases due to protein deposition around the leads thereby sealing the connection. However, the "crosstalk" may be manifested in the event that new non-Cordis leads are connected to the Gemini pacers which have two anodal rings. This would be applicable to all 1200 pacers.

OMD should evaluate the adequacy of the Cordis Notification re "crosstalk" included in the 415A Final Clinical Report sent to clinical investigators in June 1984.

Victor Spanioli
Investigator
Miami Resident Post

ATTACHMENT 6
(4 pages)

POLYURETHANE LEAD DEGRADATION PROBLEM

PRODUCT: (1) Polyurethane leads, cardiac leads models 322-745 & 322-769 and spinal lead (model 961-102) manufactured from [redacted] polyurethane; (2) leads model 326-168 manufactured with [redacted] polyurethane and [redacted] PMA P810021; (3) Leads model 326-166 manufactured with [redacted] and [redacted]

PROBLEM: (A) The firm has conducted animal testing for the degradation of the material used in the leads. [redacted] polyurethane had shown degradation cracks to a depth of 38 microns after one year of implant (FD 483 #1, Exhibit #17) in rabbit muscle. The tubing thickness is 127 microns. The firm ceased testing after the 1 year rabbit implant test results in November 1982; however, leads remain implanted in patients (FD 483 #11 of the 4/16-5/15/84 EIR) Models 322-745, 327-769, and 961-102).

(B) [redacted] polyurethane with [redacted] implanted in rabbit muscle for 6 months showed degradation to a depth of 25 microns (FD 483 #5 & 6), Model 326-168. Two year testing showed degradation to a depth of 34 microns FD 483 #3 of the 4/16-5/15/84 EIR.

(C) [redacted] with [redacted] implanted in rabbit muscle for 6 months showed nominal surface micropitting after 6 months, Model 326-166. The firm's response to the FD 483 stated that the [redacted] had dislodged and there was no silicone elastomer degradation. This [redacted] dislodgement may also pertain to the [redacted] polyurethane leads with [redacted]e.

The two cardiac leads with [redacted] were tested in clinical trials prior to January 1981. The firm did not recover additional leads shipped to physicians conducting the clinical trial. For [redacted] with [redacted] there were 177 leads distributed, 64 implanted and 113 unaccounted for. (Reference: page 11 of the 3/15-4/6/84 EIR.)

For [redacted] with [redacted] there were 17 leads used in the clinical trial ending January 1981 (page 23 and 24 of the 4/16-5/15/84 EIR). There are 63 leads still unaccounted for which were distributed with the study and never recovered (FD 483 #40 of the 6/20-8/10/84 EIR).

COMPLAINTS: There have been no complaints concerning the leads degrading in patients.

HAZARD: The hazard involved with the degradation of leads is that if a lead cracks completely through, it will short out and the pacemaker system will cease to function. This failure will be sudden and is potentially hazardous to pacer dependent patients.

Also, in the firm's response to the FD 483 concerning the micropitting of [redacted] filled with [redacted], nominally deep surface micropitting of [redacted] filled with [redacted] referred to in Report 23-03866 was caused by the dislodgement of [redacted] particles, not silicone elastomer degradation. (Corrected response to FD 483 #5 of the 4/16-5/15/84 EIR). The hazard with [redacted] dislodging is that particles will enter the lungs (from the right side of the heart) and may cause pulmonary embolization. [redacted] is insoluble and may build up in patient's lungs.

A factor that may mitigate the hazard is that the portion of the cardiac leads in blood vessels may have fibrogen form on them which may effect degradation. A large portion of the cardiac leads including the suture sleeve area is in the pacer pocket and not in the blood vessel.

The following amount of leads were distributed:

Models 322-745 and 322-769 - [redacted] polyurethane cardiac leads - 235 leads were distributed.

Model 326-168 - [redacted] polyurethane [redacted] cardiac leads - 177 distributed, 64 used in the study and 113 unaccounted for.

Model 326-166 - [redacted] with [redacted] cardiac leads - there were 15 implanted and 63 leads unaccounted for.

Model 961-102 - [redacted] polyurethane spinal leads - 195 distributed.

There are 685 patients involved with the various leads.

REFERENCES:

EIR 3/15-4/6/84 - Entire report and FD 483 #1-9, 14-18.
EIR 4/16-5/15/84 - FD 483 #1-6 and 11.
EIR 6/20-8/10/84 - FD 483 #40.
Firm's 7/3/84 response to the 5/15/84, FD 483. This states that the surface micropitting was actually dislodgement of [redacted] particles. This response is attached.

Samples: 84-374-543 - Cardiac Lead Atrial Model 322-769.
84-374-544 - Cardiac Lead Ventricle Model 326-168.

Stephen J. Tunks
Investigator, 171
Miami Resident Post

[illegible] 305-551-2000
[illegible]

ATTACHMENT C

July 3, 1984

JUL 6 1984

Mr. Adam J. Trujillo
District Director
Food and Drug Administration
7200 Lake Ellenor Drive, Suite 120
Orlando, FL 32809

Dear Mr. Trujillo:

Three errors have been discovered in the Cordis responses to the FD 483 Inspectional Observations sent to you on June 29, 1984. Please replace the originals with the enclosed corrected copies:

1. FD 483, dated April 6, 1984. Response to Observation 13; "Exhibit 13-3" deleted.
2. FD 483, dated May 5, 1984.
    a. Response to Observation 3, word processor dropped part of response in final printing.
    b. Response to Observation 5, "model 3" should read "model 326-166".

Sincerely,

Harold Hershenson

Harold Hershenson
Executive Vice President
Operations

HH:ds

Encls.

cc: J. Casey

CORRECTED - 7/3/84 ATTACHMENT G

FDA Observation

5. The firm had clinical testing of pacemaker leads (electrodes) manufactured with [redacted] used in model 326-166. The material has shown nominally deep surface micropitting after 6 months implant in rabbit muscle. The firm has failed to notify physicians of the degradation of these leads. The 6-month testing was available on 6/9/83.

Cordis Response

Cordis disagrees with the conclusion made in this observation that the observed micropitting of model 326-166 represents degradation or institutes a product defect as to which physicians should be notified. The "nominally deep surface micropitting" of [redacted] filled with [redacted] referred to in Report 23-03366 was caused by the dislodgement of [redacted] particules, not silicone elastomer degradation, and was detected at 500X magnification. Also, there have been no reports of failures due to micropitting of model 326-166 leads made with this material.

(1 page)

BALLOON TIPPED CATHETERS

PRODUCT: Torque Control Balloon Catheter, Double Lumen open end, all models. The torque control balloon catheter is used for the selective injection of hemostatic agents, drugs and radiopaque media; hemorrage control and monitoring of cardiovascular system pressures. The models involved with this particular problem are: 530-712, 530-713, 530-722, 530-723, 530-724, 530-812, 530-813, 530-822, 530-823, and 530-824.

PROBLEM: Hazard Complaint - 02414 dated 8/16/83 (exhibit #86 to 4/16-5/15/84 EIR) concerns a catheter which separated at the site of the butt fuse due to incomplete flow at fusing. The tip of the catheter separated in a patient in Hof, Germany and was retrieved under very difficult circumstances. The regular complaint file was not reviewed.

The firm's manufacturing procedures remained the same after receiving the complaint; however, the firm implemented a new inspection procedure of using a hooked tipped probe. The new inspection procedure employes a hook tipped probe to check the fusing on the interior of the large lumen. For a randomly selected period of time, the reject rate went from 3.55% (25 of 704 examined) before using the hook tipped probe to 19.94% (69 rejects in 346 examined) after implementing the use of the hook tipped probe. (pp. 24-26 & FD 483, #7 and 8 to the 4/16-5/15/84 EIR). The firm continued to sell balloon tipped catheters on hand without subjecting them to the new inspection procedures of using the hook tipped probe. On 5/15/84 (the date the FD 483 was given) the firm had 424 balloon tipped catheters on hand which had not been checked with the hook tipped probe. On 6/1/84 the firm had 354 remaining (a sale of 70 catheters). On 6/5/84 the Manager of Angiographic Product Assurance stated that the firm plans on continued selling of the balloon tipped catheters without any additional inspection (p. 41 and 42, FD 483 #10 to the 4/16-6/5/84 EIR). Sample DOC 84-374-548 dated 6/12/84) covered the sale of 30 balloon tipped catheters to Hong Kong.

COMPLAINTS: See above.

HAZARD: The tip separated and the catheter is used in the heart to monitor blood pressure. A tip separation could adversely affect patient health. The balloon tipped catheters manufactured prior to the use of the hook tipped probe are subject to a higher failure rate than those manufactured later. On 5/15/84 there were 424 balloon tipped catheters on hand which had not been checked with the hook tipped probe. The firm plans on selling these balloon tipped catheters without further inspection.

REFERENCES:

EIR 4/16-5/15/84, FD 483 #7 and 8, pages 24-26, 36 and 39.

EIR 4/16-6/5/84, FD 483, #10, pages 41, 42, and 43. Sample DOC 84-374-584.

Stephen J. Tunks
Investigator, 171
Miami Resident Post

ATTACHMENT I

(1 page)

ADEQUACY OF POLYPROPYLENE FEEDTHROUGH PROTECTION

PRODUCT: Gamma Models 308, 333B7, 335B7, 340A, 33[illegible], 334A, 336A, 336B, 337A, 402A; Sequicor 233F; and Gemini Models 415A and 415R.

PROBLEM: [redacted] may not adequately protect cell feedthroughs resulting in lithium attack on glass feedthroughs which could lead to self-discharge. As of August 1, 1984, there have been a total of 110 failures from a total implant population of 31,325 pacers that incorporate [redacted] protected cells. Twenty-three of these failures are classified as early battery depletions (EBD); however, the exact mechanism of failure for 22 of these is unknown, but is believed to be due to feedthrough degradation resulting from an inadequate [redacted] seal. One of the 23 EBDs resulted from a feedthrough short. The firm has identified other mechanisms which resulted in random early battery depletion such as "production shorts" and "collector weld failures".

Please refer to EIRs dated: 1/17-4/2/84 (pages 47-51); 4/4-5/18/84 (pages 26 and 27); 4/16-6/26/84 (pages 5-12); and memoranda dated: June 19, 1984 titled "Test Reports Relating to Cordis Corporation 510(k) Notification re [redacted] and [redacted] Cell Feedthrough Protection dated April 4, 1984", endorsed to HFZ-450; June 22, 1984, titled "Memorandum of Meeting between Norman R. Weldon, President, Cordis Corporation, et al. and James A. Casey, et al"; and June 27, 1984, titled "Long-Term Reliability, Gamma Pacemakers Containing [redacted] Protected Feedthroughs". Cordis' position is expressed in Dr. Weldon's letter to Mr. Trujillo, attached to the June 22, 1984, memorandum, and in the first two monthly updates concerning the performance of the [redacted] population dated July 17, 1984 and August 13, 1984. The Miami Resident Post had requested monthly updates concerning the performance of the [redacted] cell population including lots 4280 and 4380 which have the highest failure rates in the [redacted] group.

COMPLAINTS: Similar to those reported for pacers subject to the December 5, 1983, Gamma Notification letter, e.g., not output, low output, loss of capture, loss of sensing, etc.

HAZARD: Same potential for patient hazard as reported for the Gamma pacers which did not have protected feedthroughs.

Victor Spanioli
Investigator
Miami Resident Post

ATTACHMENT J
(8 pages)

ORTHOCOR II, 284A ANTITACHYCARDIA PACER

PRODUCT: The Orthocor II 284A antitachycardia pacer, IDE G840004, will give electrical impulses to the heart in one of the five programmed modes to get patients out of tachycardia. The pacer may also function as a regular programmable pacer.

PROBLEM: Pacers (two external 284A pacers and seven 284A implantable pacers) have recently been shipped to Europe for clinical trials on a limited basis. IDE approval is pending before clinical trials start in the United States.

The potential problem centers around the pacer falsely sensing electromagnetic interference (EMI) as tachycardia.

COMPLAINTS: No complaints. During animal testing, one dog went from ventricular tachycardia to ventricular fibrillation several times when the pacer fired its programmed antitachycardia mode.

HAZARD: The hazard of falsely sensing EMI as tachycardia is real. If the pacer receives the correct amount of programmed tachycardia recognition pulses, it will go into the programmed antitachycardia mode. If the patient is not in tachycardia, the pacer may place the patient into tachycardia. Also, ventricular tachycardia has been known to degenerate to ventricular fibrillation. If a patient had their ventricular tachycardia degenerate to ventricular fibrillation, the patient would not get sufficient blood flow to various parts of the body. The hazard may be exacerbated due to the amount and type of electromagnetic interference encountered.

Also, the firm had no procedures for antitachycardia testing. The pacer is tested a 6 Hz for tachycardia recognition and 10 Hz for noise rate. If EMI is received between 6Hz and 10Hz, the pacer will either go into the antitachycardia mode or go into the noise rate depending on the pacer.

The firm's EMI testing has a minimum susceptibility requirement of 6.3 V/M at 450 MHz for the noise rate and antitachycardia rate. The actual minimum noise rate may vary as exampled by some pacers which pick up the noise rate at 2.0 V/M at 300 MHz. The firm has failed to validate the use of their minimum susceptibility rate.

REFERENCES:

EIR 6/20-8/10/84, FD 483 #1-39 & 41.

A copy of the FD 483 for this inspection is attached.

Stephen J. Tunks
Investigator, 171
Miami Resident Post

ATTACHMENT K (3

Memorandum

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

TO : Supervisory Investigator, HFR-4575
Miami Resident Post

DATE: August 20, 1984

FROM : Investigator, HFR-4575
Miami Resident Post

Firm: Cordis Corporation
10555 W. Flagler St.
Miami, FL 33172

SUBJECT: Out of Specification Pacemakers
Offered as Charity Pacers.

Pursuant to assignment memorandum dated August 10, 1984 (M-60) from James A. Casey, Supervisory Investigator, Miami Resident Post, the requested information concerning "charity" pacers distributed by Cordis Corporation is as follows:

The firm has distributed ("donated") a total of 29 "charity" pacers between January 27, 1982 and June 12, 1984, according to available records obtained during the recent July/August inspection of the firm. A total of six physicians received these pacers for which the firm gave no warranty.

TO: Compliance Branch, HFR-4240
Orlando District

August 20, 1984

This memorandum discusses the firm's practice of donating out-of-specification pacers. The Miami Resident Post is not aware of OMD policy concerning this practice. We are requesting review of this matter and a determination as to its appropriateness. If this practice is acceptable, then we would like guidance on the nature of regulatory requirements, such as GMPs, need for 510(k) and PMA supplements, and the issue of foreign distribution of pacers donated to U.S. physicians.

Victor Spanioli
Acting Supervisory Investigator
Miami Resident Post

cc: HFZ-450 (Rahmoeller)
HFZ-300 (Gundaker)
HFR-4250
HFR-4575 (Casey)

Buy U.S. Savings Bonds Regularly on the Payroll Savings Plan

ATTACHMENT K

Inspection revealed that a total of 20 pacers were given to Dr. Philip Littleford on or about June 12, 1984. Reportedly, Dr. Littleford informed Cordis that he was taking these pacers to Poland. Ten of the pacers were out-of-specification in accordance with Cordis standards due to the pacers' having exceeded their "Use Before" dates. These pacers were listed in a letter, with Cordis letterhead, dated June 12, 1984, and involved pacer models 333D7, 237A, 217A, and 334A. The other approximately 10 pacers had their "Use Before" dates extended as per Cordis procedures. According to the firm, these pacers may have been delivered to Dr. Littleford by a salesman. He is located at 2400 Bedford Road, Orlando, FL 32803.

Pacer Model 337A-22008, donated to Dr. Roberto Reyna, 3661 S. Miami Avenue, Miami, FL 33133, was out-of-specification for the Programmed Rate 30 ppm parameter. The actual reading was 28.30 ppm (Cordis Standard: Minimum 28.31 ppm). This donation was covered by Cordis letter dated October 13, 1983, which stated the above information and that there was no warranty for the pacer.

Pacer Model 337A-8554, donated to Dr. Robert Reyna, was out-of-specification for the Haversine Sensitivity parameter at 40 Hz. The actual reading at the 60 rate was 4.6 mV (Cordis specified limit is less than 4.5mV). Cordis accompanying letter dated April 5, 1983, stated the above information and that there was no warranty.

Pacer Model 337A-9941 donated to Dr. Reyna was out-of-specification for the 7 mA (high) output current parameter. The actual reading was 6.3 mA (Cordis standard 7.0 (+1.0, -0.5) mA). Cordis letter dated December 6, 1982, accompanied the donation and stated that the pacer was not under warranty as it did not meet the 7 mA output current specification.

Pacer Model 337A-4824 was donated to Dr. Alex Furst, also at 3661 S. Miami Avenue, Miami, FL 33133. The pacer was out-of-specification for the 7(high) mA output current parameter. Cordis specification limits is 7.0 (+1.0, -0.5) mA and the actual reading was 6.3 mA. Cordis letter dated November 1, 1982 included this information and that there was no warranty accompanying the pacer. This pacer was implanted into Doris Ferguson at Mercy Hospital, Miami, FL, by Dr. Marvin Erbersfield according to the Implanted Pacer Registration form submitted to Cordis.

Pacer Model 237A-6647 donated to Dr. William Batiuchok located at 146-43 Beach Avenue, Flushing, NY 11355, was out-of-specification for the 7(high) mA output current values. The actual reading of the pacer was 6.4 mA. Cordis letter dated July 23, 1982, indicated the above information and that there was no warranty accompanying the pacer.

ATTACHMENT A

Pacer Model 327A-4446 also donated to Dr. Batiuchok was out-of-specification for output current at 7(high) mA. The pacer actually read 6.4 mA. Cordis letter dated July 23, 1982, included the specification data and that there was no warranty accompanying the pacer.

Pacer Model 337A-5548 donated to Dr. James Jude also located at 3661 S. Miami Avenue, Miami, FL 33133, was out-of-specification for current output at 7(high) mA. The actual reading was 6.4 mA. Cordis letter dated February 25, 1982, accompanied the pacer. The letter states the specification data and absence of warranty. This pacer was implanted into patient Hazel Rolle on March 1, 1982, at Mercy Hospital by Dr. Marvin Ebersfeld.

Pacer Model 337A-11240 donated to Dr. Richard Thurer, University of Miami School of Medicine, Miami, FL 33101, was out-of-specification for the 5.5 mV positive sensitivity parameter. The actual pacer reading was 6.2 mV (Cordis specifies 5.5 (± 0.5) mV. The unit was accompanied by Cordis letter dated January 27, 1982, stating the specification data and the absence of a warranty. According to Cordis Implant Pacer Registration, the unit was implanted into patient Maria Valdes at Palm Springs General Hospital, Hialeah, on September 3, 1982, by Dr. Roberto Reyna.

Pacer Model 334A-7127, donated to Dr. Thurer, was out-of-specification for current output at 7(high) mA. The pacer read 6.4 mA. The unit was accompanied by Cordis letter dated April 14, 1982, which included the specification data along with the warranty disclaimer. This unit was implanted into patient Raphael Martinez on April 15, 1982, by Dr. Thurer at Jackson Memorial Hospital, Miami, FL., according to the Cordis Implanted Pacer Registration form and as verified during a recall check at Dr. Thurer involving Gamma Notification/Recall. This pacer was included in that recall.

Inspection also disclosed that the firm dispositioned 5 additional pacers, also out-of-specification, for future donations. These involved pacer Models 337A, 336A, and 233F (two). Also, a sixth pacer dispositioned for "Charity" donation, Model 337A-4823 could not be located at the firm and may have already been donated.

Veronika J. Fabritzky
Veronika J. Fabritzky

Rec'd [illegible]/31/84 [illegible]

[illegible]

Memorandum

cordis.

Pls fax to HFZ-320
Att: Joe Moore
9ORL-DO/HFR-4250
for 4240

Date: 8/31/84

To: J. Pagones/H. Hershenson Site/Location

From: F. Gregorio *F G*

Subject: Analysis of Distribution - Gas Analysis Pacers

I have completed preliminary review of the distribution and manufacturing history of Cordis pacers subjected to a gas analysis temperature of 115° C. The following is a brief summary of my findings:

A) Total pacers subjected to 115° C Gas Analysis - 251
(Models 217A, 221B7, 237A, 308A, 333B7, 333D7, 334A, 336A, 336B, 337A, 233F, 402A, 402B, 415A, 415B)

B1) # of these pacers Implanted without battery replacement - 57

B2) How many of the 57 implants were eventually explanted - 6
(3 patient expirations with no product return
2 Gamma EBD failures - no circuit malfunctions
1 233F EBD due to melted separators)

C1) # of these pacers Implanted with replaced batteries - 91

C2) How many of the 91 implants were eventually explanted - 11
(4 patient expirations with no product return
5 Gamma EBD failures - no circuit malfunctions
2 Elective explants - Pacer Ok)

Total Implants - 148
Total Explants 17

D) # of pacers sold/shipped but with no implant date - 30
(1. Without replaced batteries - 13)
(2. With replaced batteries - 17)

E) Of these 30 pacers, how many were returned to Cordis - 5
(All 5 returned due to expired Use Before Date
- none returned with any complaint)

F) Distribution of these 30 units - 17 sold to Roden
2 sold to S. America
1 sold to Canada
10 sold in U.S.

I will prepare a final report of these findings in the near future. Telex will be sent to Roden to determine if any of the 17 units sold to them were implanted and/or explanted. If explanted, copies of the Roden PSR's will be obtained. A complete listing of the 251 pacers, with pertinent information itemized, is being finalized.

cys – EM
– JJM
– [illegible]
– CCR
– JAC

To: Adam Trujillo, HFR-4200

Date: September 6, 1984

Memo of Second Ad Hoc Committee Meeting on August 30, 1984

File
Cordis F.

Attendees:

Mervin Shumate, Director, Enforcement Policy Staff (HFC-20) Chairperson
Walter Gundaker, Director, Office of Compliance (HFZ-300)
Maurice Kinslow, RFDD, Region IV (HFR-41)
Michael Landa, Associate Chief Counsel for Medical Devices (GCF-1)
David Bryant (HFO-400)
Joan Davenport (HFC-25)
Howard Schloss (HFC-25)
Bill Damaska (HFZ-320)
Tom Moore (HFZ-320)
Robert Skufca (HFZ-70)
John Samalik (HFZ-321)
Glen Rahmoeller (HFZ-450)
Don Dahms (HFZ-450)
Adam Trujillo (HFR-4200)
James Casey (HFR-4575)

Subject: Enforcement Strategy for Cordis Corporation, Miami, FL

This ad hoc committee meeting was held to consider agency strategy for Cordis Corporation in light of CDRH's health hazard evaluations of several Cordis medical devices identified by ORL-DO during their recent establishment inspections.

The Center's representatives briefed the attendees on the nature of the problems/defects associated with the various Cordis medical devices, and the basis of the Center's proposed actions aimed first at protecting the public health and, secondly, at correcting the violations. This briefing included a comparison of the significance and extent of Cordis' problems with other similar situations. The Center advised us that Cordis' problems appear to be serious and of a general nature, i.e., poor manufacturing practices involving several types of products which have been distributed to a large patient population.

The discussion next focused on hazard assessments and strategies for those Cordis products requiring immediate action and then on those requiring less urgent action or follow-up.

The following was agreed to during the meeting:

1. CDRH will draft by c.o.b. Tuesday, September 4, 1984 a letter from Mr. Villforth to Cordis setting forth what CDRH believes needs to be done with respect to the various violative devices and inviting the company to meet promptly with FDA to arrive at a plan of action to eliminate the hazards and correct the violations with the degree of speed FDA believes is indicated for each of the following:

.) various pacemakers subjected to gas analysis involving temperatures of 115 C.

.) Lambda & Theta series pacemakers with the printed wiring board problem

.) Lambda & Theta series pacemakers not having immediate burn-in, resulting in EBD

.) various pacemakers donated to charity when they do not meet Cordis' specifications

.) pacemaker programmers with incorrect instructions for use and software

.) torque control balloon catheters separating because of bonding failure

.) Gemini Model 415 A pacemakers with cross-talk problem

.) Multicor Mini-Gamma Model 340A pacemakers with polypropylene-protected feedthrough and no 510(k) submission

.) pacemakers with polypropylene feedthrough with potential for EBD and sudden output cessation

.) Orthocor II having potential for false sensing due to electromagnetic interference and which was exported with improper animal testing

2. CDRH will distribute the draft via electronic mail and, if necessary, reconvene the principal representatives (i.e., Walt Gundaker, Merv Shumate, Arthur Levine and Maurice Kinslow) to review and revise, if necessary, the draft letter.

3. The letter, as approved by the principals, will be issued by Friday, September 7, 1984. If this deadline cannot be met, the agency will begin prompt action for those products which should be subjects of Class I recalls.

4. CDRH will notify the (two) foreign countries receiving Cordis' Orthocor II device which has not been approved for investigational use or marketing in the U.S., that the export approval is being withdrawn because of potential for EDB and sudden output cessation.

5. Following this August 30th meeting, the principals will brief their respective office heads on the strategy developed in this meeting.

6. The GMP inspection will be targeted for mid-September with intentions of limiting it to one month.

7. A recent bio-research monitoring inspection of Cordis Orthocor II pacers disclosed poorly conducted animal studies. The report is being reviewed by CDRH. A bio-research inspection of Orthocor I pacers, which have an approved IDE, will be scheduled, but not until after the GMP inspection.

8. Mr. Shumate pointed out that the apparent violations are so far ranging and serious that everyone should be aware of the potential for criminal prosecution and conduct themselves accordingly. For example any substantive discussions should be reduced to writing for the record. Everyone was advised to make certain they routinely copy Tom Moore who will be the repository for all activities. Further, the committee will be available throughout this investigation to deal with questions involving policy, priorities and strategies.

/s/
Joan E. Davenport

Draft:JED:gbd:8/31/84
Revised:9/4/84:Landa
Damaska/Gundaker
Trujillo/Kinslow
RT:Draft:gbd:9/4/84
Init:DHBryant:9/4/84
Revised:Shumate:9/4/84

cc: All Attendees
HFC-1 (Hile)
HFO-2 (Ottes)
HFC-30 (Brisson)
HFC-25 R/F
GCF-1 (Levine)
HFA-224

Received via DEC 9-7-84:dar

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

SEP 7 1984

Norman R. Weldon, Ph.D., President
Cordis Corporation
10555 West Flagler Street
Miami, Florida 33172

Dear Dr. Weldon:

As you are well aware our Orlando District Office has been conducting a series of recent inspections in your Miami manufacturing facility. The Center for Devices and Radiological Health (CDRH) has reviewed and evaluated the information obtained during these inspections and I would like to call to your attention a number of serious health concerns.

1. Gamma Models 308A, 333B7, 333D7, 334A, 336A/B, 337A, 402A/B, Gemini Model 415A/R; Sequicor Models 233 F/G; and Theta Models 217A, 221B7, and 237A:

The FDA inspection revealed that approximately 251 of these pacemakers had been subjected to [redacted] testing involving high temperatures 100+ → of [redacted]C or above. In spite of the pacemakers and their internal components being subjected to elevated temperatures for undetermined periods of time they were distributed and approximately 150 were implanted. Some of these pacemakers were reworked by replacing the battery cells with cells which had not be subjected to the high temperatures reached during the [redacted] test. The rest contained battery cells which were subjected to the elevated temperatures during the [redacted] test. Subsequently, explanted pacemakers revealed failures due to early battery depletion (EBD). We understand that you have stopped this practice.

In our opinion, pacemakers subjected to high temperatures for undocumented periods of time may result in serious adverse health consequences in pacemaker dependent patients as a result of EBD and sudden no output failure. We recommend that all physicians and hospitals to whom these pacemakers have been distributed be immediately informed of this serious potential problem and pacemakers not implanted be recalled. You should also consider advising physicians of the need to make an assessment of whether selective explants are a prerequisite for those pacemakers implanted with the nonreplaced batteries. We request 100% accountability of all pacemakers subjected to the [redacted] test at elevated temperatures.

2. Lambda Series Models 188A7/B7, 190A/E, 206A/B, 208, 215, 235, 236; Theta Series Models 221A7/B7 and 217; Stanicor Q-238B7; Stanicor R-241:

   These pacemakers have had failures because of failed printed wiring boards and because early batteries were not burned-in as required by Cordis specifications. Many of these pacemakers have been distributed and implanted (1) with defective printed wiring boards that had not been modified in an effort to correct the failures by filling the open plated through-holes, and (2) without subjecting the [redacted] cells to immediate burn-in as required. Distribution of pacemakers with these defects has resulted in complaints of sudden no output and EBD, resulting in a 2-3% failure rate.

The "correction" was not reviewed by FDA since no 510(k) premarket notification was submitted describing the problem or the resulting modifications. Based on the data that we have obtained, we believe that these deficiencies expose pacemaker dependent patients to potential serious adverse health consequences as a result of sudden no output failure.

It is our opinion that the prior Product Updates which you have issued were not adequate to warn physicians of these serious problems. We, therefore, recommend that you promptly notify all physicians and hospitals of these serious problems.

3. Various "Charity" Pacemakers:

   The FDA inspection revealed that between January 27, 1982 and June 12, 1984 your firm distributed at least 29 out of specification pacemakers as charitable contributions to physicians. These were apparently supplied free of charge and without a warranty. This practice constitutes distribution of adulterated pacemakers under the Federal Food, Drug and Cosmetic Act (FD&C) and must be discontinued immediately.

We recommend that you identify any additional out of specification pacemakers and recall those not implanted. In addition, we request that you determine the implanting physician for each of the out of specification pacemakers and assure that each physician, if different from the physician receiving the pacemakers, has been notified of the out of specification status of the unit implanted.

4. Pacemaker Programmer Models 255 A III and 256 IAP:

> Many of these programmers may have instructions for use and software which do not match, thereby causing confusion on how to program Models 233F and 415A pacemakers. This confusion includes program stats that may falsely indicate end-of-life battery conditions. This deficiency may result in unnecessary explantation and replacement of the pacemakers, exposing the pacemaker patient to the risk of additional surgery.

We request that you submit PMA supplements for all revisions, advise us of any other pacemaker model numbers affected, and stop distribution of these programmers and revisions (software) until the supplements are approved. We recommend that all physicians and hospitals that have these programmers be notified of the problem.

5. Gemini Model 415A Pacemaker:

> Of the approximately 1200 [redacted] pacemakers implanted in the clinical study, we understand that "crosstalk" is a potential problem with the 190 investigational pacemakers implanted with two non-Cordis leads. The problem has occurred in pacemakers with [redacted] when two non-Cordis leads were used. When some non-Cordis leads were used, it appears that body fluid leaked into the connector. The [redacted] and the presence of body fluid in both cavities of the connector result in an unanticipated "crosstalk".

FDA was not notified, as required by the provisions of the investigational device regulations, of the unanticipated adverse device effect (21 CFR 812.150) of this "crosstalk". In addition, neither your firm's 1983 IDE Progress Report nor your 1984 Final IDE Report adequately discussed the "crosstalk" complaints that Cordis received.

It appears that inappropriate inhibition of the ventricular channel because of "crosstalk" may result in significant health consequences in pacemaker dependent patients. We request that you submit complete documentation of all clinical complications relating to Gemini and Sequicor pacemakers to include the brand and model number of each pacemaker lead associated with complications, to the Center. We recommend the issuance of a "Safety Alert" by your firm to all investigators that were involved in this IDE.

6. Multicor "Mini-Gamma" Model 340A Pacemaker With [redacted] Protected Battery Feedthrough:

These pacemakers are being manufactured and distributed without submission of a 510(k) notification.

We request your firm stop marketing this device until a 510(k) is submitted on this pacemaker and battery, and a substantial equivalency decision is made.

7. All Pacemakers With [redacted] Protected Battery Feedthrough:

These pacemakers may have the potential for EBD and sudden no output failure due to inadequate sealing of the battery feedthrough. No 510(k) premarket notification was submitted when [redacted] was originally incorporated as a battery feedthrough protection; and we have not completed our review of your recent 510(k) submission for this change.

Therefore, we request that you stop distribution of all pacemakers in stock that contain [redacted] protected battery feedthrough until a substantial equivalency decision is made by FDA. In addition, we request that you continue to provide monthly reports concerning the effectiveness of [redacted] protected battery feedthrough. We are also requesting that a cumulative survival of Gamma pacers with protected cells and unprotected cells at 12, 24, and 36 months be provided to the Center.

8. Torque Control Balloon Catheters, Models 530-712, 530-713, 530-722, 530-723, 530-724, 530-812, 530-813, 530-822, 530-823, 530-824:

These catheters may have the potential problem of separation of the tip from the catheter body due to bonding failure. This potential defect represents a potential hazard of catheter embolization. The FDA investigation revealed that your firm implemented a new inspection procedure of using [redacted], after finding the problem of [redacted]

No 510(k) premarket notification was submitted for this modification which FDA believes could affect the safety of this device. The FDA investigation revealed that there was a significant increase in the rejection rate after the new inspection procedure was implemented. However, there are a number of catheters in stock that have not been tested by this procedure which are being distributed. We request that you stop marketing these catheters and test all of the catheters currently in stock by the new inspection procedure. In addition, prior to redistribution of all catheters, submit a 510(k) premarket notification which will include a failure analysis, comparative tests using the new and the old procedures and an explanation of how the prevention of such failures will be assured.

9. Orthocor II, 284A Antitachycardia Pacemaker:

> Based on the data that FDA has, it appears that Cordis did not submit complete animal testing on this device and that Cordis has not complied with Good Laboratory Practices in conducting the animal studies. It appears that this pacemaker [redacted] may have a potential for false sensing due to electromagnetic interference.

On August 17 and December 19, 1983, Cordis requested approval to export this pacer to the Netherlands and Venezuela. The Center approved the request on November 14, 1983 and April 30, 1984. That approval is hereby withdrawn until complete animal data is submitted for review by the Center and a new export approval is issued. Therefore, you must immediately cease exporting these pacemakers, and we recommend that you recall all of them not yet implanted.

Please respond within five (5) days as to what action you intend to take to comply with our requests and recommendations. If you wish to meet with the FDA to discuss this letter, please contact Mr. William H. Damaska at 301-427-7218. A meeting will not be necessary if, at this time, you initiate appropriate corrective actions.

In conclusion, I must say that the problems referred to in this letter appear to reflect a corporate practice and a pattern of serious disregard for the requirements of the Federal Food, Drug and Cosmetic Act. I do request your prompt attention and appropriate action on these matters.

Sincerely yours,

John C. Villforth

John C. Villforth
Director
Center for Devices
and Radiological Health

cc: William Y. Murphy, Jr., M.D.
Chairman of the Board
Cordis Corporation
10555 West Flagler Street
Miami, Florida 33172

9C

emorandum

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

: Supervisory Investigator, HFR-4575
Miami Resident Post

DATE: September 10, 1984

: Investigators, HFR-4575
Miami Resident Post

Mfr.: Cordis Corporation
10555 W. Flagler St.
Miami, FL 33172

: Hand-Delivery of Letter from
Mr. Villforth to Dr. Weldon,
Cordis Corporation, dated
September 7, 1984

On September 7, 1984, we were requested by Supervisory Investigator James A. Casey to deliver a letter dated September 7, 1984 from John C. Villforth, Director, National Center for Devices and Radiological Health (attachment 1). Mr. Casey had informed us that the original of the facimile copy of the letter we were to present to Dr. Norman Weldon, President, and Chief Executive Officer, Cordis Corporation, was being air expressed on September 7, 1984. Since the letter stated that Dr. Weldon had five days to respond to the letter, he was being provided with a copy of the letter as soon as possible.

At approximately 3:45 p.m. on September 7, 1984, we arrived at Cordis Corporation. We requested to see Dr. Weldon and were told by the receptionist that Dr. Weldon was unavailable to meet with us at the present time but Mr. Harold Bershenson, Executive Vice President, would meet with us. Mr. Bershenson met us along with Mr. John N. Pagones, Vice President, Corporate Product Assurance, in Mr. Pagones' office. Mr. Bershenson reaffirmed that Dr. Weldon was unavailable at the present time, otherwise he would have seen us. A photocopy of the letter to Dr. Weldon was given to both Mr. Bershenson and Mr. Pagones. Mr. Bershenson was asked if Dr. Weldon would be available later on. Mr. Bershenson stated he did not know but he would contact Dr. Weldon to find out when he would be available.

TO: District Director, HFR-4200
Orlando District

September 10, 1984

Cordis has always been provided an opportunity to respond whenever Inspectional Observations, FD-483, have issued.

James A. Casey
James A. Casey
Supervisory Investigator
Miami Resident Post

cc: HFZ-1
cc: HFZ-320 (faxed 9/10/84)
cc: MIA-RP/JAC
Copy faxed to HFR-4200 9/10/84

HFZ-1

Buy U.S. Savings Bonds Regularly on the Payroll Savings Plan

Mr. Hershenson and Mr. Pegones proceeded to read the letter. Mr. Hershenson commented, as he read the portion of the letter pertaining to the balloon tipped catheters, that he felt the Agency's position "was ridiculous as there had been only one complaint". Both Mr. Hershenson and Mr. Pegones commented that they did not believe that FDA had read Cordis' responses to the concerns expressed by FDA during inspections, and in some instances, Cordis had not yet responded to some of the concerns expressed in the letter such as, the Orthocor II situation and the crosstalk problem. Mr. Hershenson stated that he did not feel the Agency was being objective in the requests that were made in the letter. Mr. Hershenson stated that the firm would have to study the letter in detail and then prepare the firm's response to the letter. Mr. Hershenson was told that FDA did not expect an immediate response and that the only reason for our visit was to hand-deliver the letter to Dr. Weldon. Mr. Hershenson stated that he would contact Dr. Weldon to see if he could meet with us.

Shortly thereafter, Mr. Hershenson returned and stated that he had been in contact with Dr. Weldon and he would be able to meet with us. We proceeded to Dr. Weldon's office and both Mr. Pegones and Mr. Hershenson again stated that they felt the Agency had not adequately reviewed Cordis' responses and had not been objective in their evaluation of the areas of concern. In particular, Mr. Hershenson stated that the action requested by FDA concerning the Lambda and Theta pacers was extreme in that those pacers had a 92% cumulative survival after 7 years.

We met Dr. Weldon in his office at approximately 4:05 p.m. and Investigator Spanioli informed him that we were providing him with a facsimile copy of a letter issued from Mr. Villforth's office which requested that he and Cordis Corporation respond within five days. Dr. Weldon asked when the five day period started. Investigator Spanioli informed him that he did not know, but that he could contact Mr. William Damaska at the telephone number stated in the letter.

Dr. Weldon proceeded to read the letter and commented as he finished reading it, "This is s__t." Dr. Weldon added that we "could quote him on that" after he observed Investigator Tunks taking notes. Dr. Weldon appeared to be distressed and upset and stated that he had lost count of the number of recalls being requested by FDA. He also complained about the request to discontinue distribution of the Orthocor II and the pacemaker programmer. Dr. Weldon stated "What's going on here? Are we really so out of touch?" Dr. Weldon then stated, "I don't believe we have been treated fairly or equitably". Investigator Spanioli stated to Dr. Weldon that many individuals at the Center for Medical Devices had reviewed the inspectional findings and documents obtained from Cordis and also the Cordis responses and had reached the conclusions stated in the letter. Dr. Weldon interjected that yes FDA had reviewed those records and other records received from non-FDA sources as well. Dr. Weldon then stated that he better not make any additional comments prior to speaking with an attorney as he noted Investigator Tunks was writing down his comments.

Mr. Bershenson stated again that he did not believe FDA had been objective in that he did not feel that FDA had read the Cordis responses nor had they afforded Cordis an opportunity to express their views with respect to other issues cited in the letter that Cordis had not yet responded to. Mr. Bershenson emphasized that Cordis had not yet responded to some FDA 483's that related to concerns expressed in the letter.

Mr. Pagones asked if Don Dahms, Division of Cardiovascular Devices, had been involved in the preparation of the letter. Investigator Spanioli informed Mr. Pagones that he believed that Mr. Dahms also participated in the review of Cordis reports. Mr. Pagones then stated, apparently to Dr. Weldon and to Mr. Hershenson, that Mr. Casey also participated in the discussions held at OMD concerning the Cordis situation.

Dr. Weldon stated that the firm would have to review the letter and prepare a response. Dr. Weldon was offered Mr. Villforth's telephone number. Initially Dr. Weldon stated he had no intention of speaking with Mr. Villforth; however, he then asked for the telephone number which was provided by Investigator Tunks.

Investigator Spanioli stated that one of the photocopies of the letter given to Mr. Bershenson and Mr. Pagones was intended for Dr. William P. Murphy, Chairman of the Board. Dr. Weldon responded by stating that "Dr. Murphy, as of yesterday, (September 6, 1984) no longer had any management role in the company." Investigator Spanioli asked if Dr. Murphy had any responsibility with respect to the operations of Cordis. Dr. Weldon stated not in the sense that FDA is interested in. Dr. Weldon then added that he would provide Dr. Murphy a copy of the letter.

We then departed Dr. Weldon's office along with Mr. Bershenson and Mr. Pagones who escorted us to the lobby. Mr. Bershenson again expressed his disbelief in the contents of the letter and added that Cordis would have to consider their position and respond to FDA.

Victor Spanioli

Stephen J. Tunks

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS
7200 Lake Ellenor Drive #120
Orlando, FL 32809
(305) 855-0900

NAME OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: [illegible]

TITLE OF INDIVIDUAL
VP [illegible] Assurance

FIRM NAME
Cordis Corporation

STREET ADDRESS
10555 W. Flagler St.

CITY AND STATE
Miami, FL 33172

DATE OF INSPECTION
9/14,18-21,27 & 10/1-3, 5, 9 &10/84

C. F. NUMBER
1016427

TYPE ESTABLISHMENT INSPECTED
Pacemaker Manufacturer

NAME OF FIRM, BRANCH OR UNIT INSPECTED
Same

STREET ADDRESS OF PREMISES INSPECTED
Same

CITY AND STATE
Same

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

1. The Agency was not notified of significant modifications to the External Ventricular Drainage Set, a pre-amendment device, by means of a 510(k) submission.

2. Pacemakers, Model 261, were assembled and exported to include the circuitry, can, batteries. The adapter block was shipped with the pacemaker as a kit. These pacers were final tested. The firm does not have either a PMA, 510(k) or export approval for these pacemakers.

3. The firm failed to adequately notify physicians of the possible patient health hazard involved in using pacemakers subjected to gas analysis at 115° C, including pacemakers with and without replaced batteries. On 12/5/83, the firm stopped salvaging the pacemakers but did not notify physicians until 10/4/84.

a. Additionally, the firm has not notified physicians of the potential health hazard concerning Roden (Cordis Europa) manufactured pacemakers that were subjected to gas analysis at 115° C at Cordis Corporation, Miami, Florida (approximately 180 additional pacers are involved).

4. During the 7/23-8/16/84 inspection, complete records of pacemakers subjected to 115° C gas analysis were requested. The firm failed to identify 176 gamma pacemakers manufactured by the Roden facility of Cordis Europa and analyzed at 115° C in Miami, Florida from 2/26/80 to 12/27/83.

5. There was no validation studies done on pacemakers subject to gas analysis at 115° C prior to shipment to determine if subjecting the pacers to the heat would cause any malfunctions. Also the firm was inconsistent in replacing batteries of pacemakers subject to the gas analysis.

[illegible] 483 [illegible] STT 10/[illegible]

6. The firm cannot locate all travel cards (device history records) concerning pacemakers subjected to gas analysis to 115° C; therefore, the actual disposition of the pacemakers is unknown, i.e., sold, implanted, or scrapped. A [illegible] of computer [illegible] and implant [illegible] [illegible] of [illegible] or implant. STT [illegible]

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Stephen Tunks

EMPLOYEE(S) NAME AND TITLE (Print or Type)
Stephen J. Tunks, Investigator

FORM FDA 483 (12/78) PREVIOUS EDITION MAY BE USED. INSPECTIONAL OBSERVATIONS PAGE 1 OF 5 PAGES

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS
7200 Lake Ellenor Drive, #120
Orlando, FL 32809
(305) 855-0900

NAME OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: [illegible]

DATE OF INSPECTION
9/14,18-21,27 &
10/1-3,5,9, & 10/24

C. F. NUMBER
1016427

TITLE OF INDIVIDUAL
VP Corp Quality Assurance

TYPE ESTABLISHMENT INSPECTED
Pacemaker Manufacturer

FIRM NAME
Cordis Corporation

NAME OF FIRM, BRANCH OR UNIT INSPECTED
Same

STREET ADDRESS
10555 W. Flagler St.

STREET ADDRESS OF PREMISES INSPECTED
Same

CITY AND STATE
Miami, FL 33172

CITY AND STATE
Same

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

7. On 12/5/83 Cordis Corporation stopped salvaging pacemakers subjected to gas analysis at 115° C; however, they continued to sell salvaged pacemakers which underwent gas analysis at 115° C exampled by: 333D-3352 released on 6/13/84 and 333D-4181 released on 5/10/84.

8. The firm failed to document the date that they stopped salvaging all pacemakers which had been subjected to gas analysis at 115° C. The firm also failed to adequately document the date that they stopped testing crimped D battery cells at 115° C.

9. There is no pass/fail criteria for the gas analysis testing [illegible].

10. The following listed deficiencies pertain to Cordis' 20 battery cell experiment conducted from 12/2-12/7/83 and reported in a February 13, 1984, memo entitled "Investigation of Field Return Pacer 233F-9549" and in a September 20, 1984, report entitled "Gas Analysis Pacer Investigation".

a. There was not any protocol or written instructions for conducting the test. ~~or a written report of the results prepared by the employee conducting the test.~~ [illegible]

b. The information recorded in the laboratory notebook for reporting the examination of each battery cell is not consistent.

c. The notebook entries are undated, the start/stop times were not listed and the oven used in the test was not annotated.

d. The notebook entries indicate that many pacers were in the same oven at the same time, i.e., pacers at 115° C for 8 hours, 115° C for 24 hours and 125° C for 15 hours. The employee could not explain how she determined which pacer was subject to which temperature and how two different temperatures were evaluated at the same time in the same oven.

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE

EMPLOYEE(S) NAME AND TITLE (Print or Type)
Stephen J. Tunks, Investigator

FORM FDA 483 (12/78) PREVIOUS EDITION MAY BE USED. INSPECTIONAL OBSERVATIONS PAGE 2 OF 5 PAGES

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

7200 Lake Ellenor Drive #120
Orlando, FL 32809
(305) 855-0900

NAME OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: [illegible] N. Parsons

DATE OF INSPECTION
9/14,18-21,27 &
10/1-3,5,9 & 10,84

C. F. NUMBER
1016427

TITLE OF INDIVIDUAL
V.P. [illegible] Assur[illegible]

TYPE ESTABLISHMENT INSPECTED
Pacemaker Manufacturer

FIRM NAME
Cordis Corporation

NAME OF FIRM, BRANCH OR UNIT INSPECTED
Same

STREET ADDRESS
10555 W. Flagler St.

STREET ADDRESS OF PREMISES INSPECTED
Same

CITY AND STATE
Miami, FL 33172

CITY AND STATE
Same

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

e. The Blue M oven used in the experiment did not have a temperature recording device. The oven was never calibrated at the temperature used for this experiment. There was no heat distribution study on the oven. The [redacted] thermometer in the oven had never been calibrated. The reading of the thermometer was not recorded in the lab workbook at the time of test.

11. The following listed deficiencies pertain to a gas analysis study performed in March 1980 and reported in an April 10, 1980, memorandum entitled "Pacer Moisture Analysis at 115° C" and in a September 20, 1984, report entitled "Gas Analysis Pacer Investigation."

a. There was no protocol or instructions for conducting the tests.

b. There is no raw laboratory data or workbooks for the tests.

c. The 9/20/84 report states that there was no evidence of damage or adverse effect to the hermetic batteries when in fact the batteries were only visually examined. According to the employee performing the testing, the batteries were neither cut open for separator examination nor given an electrical test after exposure to 115° C.

d. The firm could not locate travel cards (device history records) for the 16 pacemakers whose circuit assemblies were reportedly tested at 93° C; therefore, the actual disposition of the pacemakers is unknown, i.e., sold.

12. The battery analysis report 23-04262 dated 7/18/84 and the lab workbook containing the raw data does not give the 233F pacemaker serial number from which the batteries were removed. Additionally, the raw data in the workbook was undated and written in pencil. The result of this failure was that Cordis Corporation confused the testing results concerning two pacemakers and erroneously reported that pacemaker 233F-8046 did not have melted battery separators.

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE

EMPLOYEE(S) NAME AND TITLE (Print or Type)
Stephen J. Tunks, Investigator

FORM FDA 483 (12/78) PREVIOUS EDITION MAY BE USED.

INSPECTIONAL OBSERVATIONS PAGE 3 OF 5 PAGES

P.O. Box 025700
Miami, FL 33102-5700, U.S.A.
Telephone 305-551-2000
Telex 6811112

cordis

September 17, 1984

John C. Villforth
Director (HFX-1)
Center for Devices and Radiological Health
8757 Georgia Avenue
Silver Spring, MD 20910

Dear Mr. Villforth:

This letter documents the information that Cordis intends to present at its meeting with you on September 18, 1984 in response to your letter of September 7, 1984. We appreciate your meeting with us to discuss these issues.

As you may know, the Orlando District Office inspected Cordis almost continuously between December 3, 1983, and August 10, 1984, and has presented ten different sets of FD 483 Investigational Observations to Cordis. Cordis has been reviewing all of these observations carefully and so far has provided to FDA point-by-point responses to six of the FD 483 reports. Also, as a result of these reviews, Cordis has initiated a number of improvements in its policies and procedures.

Cordis believes, however, that some of the FDA observations were incorrect or drew the wrong inferences. The Cordis point-by-point responses were intended to clarify facts as to these observations, but Cordis is concerned that its responses have not been completely understood or considered by FDA. Also, FDA has had no opportunity to consider Cordis responses to the last four FD 483 reports because they have not yet been submitted. At the meeting and in this letter Cordis plans to present and discuss information which it believes will clarify the various situations addressed in your letter with the purpose of reaching agreement as to the issues involved and as to what actions Cordis should take to meet the Agency's requirements.

Cordis appreciates and shares FDA's concern about the potential health consequences of the situations under discussion and will take the appropriate actions to minimize any adverse effects. However, Cordis also wants to avoid taking actions which may have been requested as the result of incorrect or incomplete information and which are not necessary or beneficial to public health.

The following comments address, in the same order, each of the topics included in your September 7th letter:

1. Heat-Stressed Pacers

Cordis is concerned about the unintended exposure of 251 pacers to temperatures of up to 125°C for 8 to 24 hours. This error resulted from a change in the test temperature at which gas analysis was conducted from 37°C to 115°C. This change was implemented to improve the accuracy of the gas analyses for moisture. The change in temperature, however, was not communicated adequately to the manufacturing group, who continued to salvage the pacer circuit, and sometimes the battery, as they had appropriately done when the analysis was performed at 37°C.

When the error was discovered, Cordis discontinued the practice and studied the effect of this heating on the reliability of the pacer components. In Cordis' judgment, the heating had no adverse effect on any components or on the service life of the pacers involved, as explained below. Under the circumstances, while Cordis regrets that this exposure to heat occurred, it believes it would be a disservice to persons in whom these pacers were implanted to overreact to this situation.

[illegible]

purpose of these "burn-ins" is to eliminate "infant mortalities" and improve reliability. Therefore, Cordis believes that additional heating during gas analysis had no adverse effect on the pacer circuits.

No crimped battery cells were salvaged and used after gas analysis, but some hermetically sealed cells were. However, Cordis has examined the components of such cells exposed in an experiment to 125°C for 15 hours or 115°C for 24 hours and found no anomalies. Also, there was no significant decrease in the electrical capacities of four cells which were subjected to the high temperature gas analysis.

One early battery depletion in an implanted pacer occurred after only three months of implant, but this failure appears to have been caused by unusual excessive heat which melted away the battery separator, resulting in electrical shorting and early depletion. The appearance of this separator was completely different from that of separators recovered from the eight other early depletion cells or from cells deliberately heated to 125°C for 24 hours, all of which had no evidence of such melting.

Except for this one shorted battery, the time to depletion ranged from 12 to 44 months, with an average of 27.6 months. All of the battery depletions occurred in pacer units which were included in the Cordis notification on Gamma cells, and their failure appears to be based on the failure mechanism as described in that notification and not due to heat exposure for gas analysis. Further, most of these depletions were detected by a rate decrease in normal monitoring and replaced before failure. Except in the case of the shorted cell described above, there is no evidence that sudden no-output failures have occurred in the heat-stressed pacers.

The cumulative survival of 92.4% at 37 months for the heat-stressed pacers, including the notification Gamma units, also indicates that reliability has not been seriously compromised by the gas analysis heat stress.

Cordis agrees that appropriate action should be taken to minimize any potential health hazard. 100% accountability of the heat-stressed pacers is being provided to the local FDA inspectors, and all units distributed and not implanted or returned will be retrieved. Because of the good reliability of these units despite exposure to heat, Cordis recommends that the monitoring physicians be informed of the situation, not by a recall or notification, but by means of a "Safety Alert" which recommends consideration of prophylactic replacement in pacer-dependent patients and monthly monitoring of others. Since the batteries are the only components which could be adversely affected by heating, Cordis recommends that this alert be sent only as to those units not included in the Gamma notification and with unreplaced batteries

2. Lambda Series and Theta Series Pacers

There have been no early battery depletions in Theta series pacers. Also, the early battery depletions in the Lambda series pacers were not due to lack of burn-in as required by Cordis specifications. All of the batteries were burned-in as specified at the time of their manufacturing. However, the burn-in process was later changed to improve voltage stability, and this change was subsequently found to have eliminated early battery depletion in the units made after it was implemented.

The printed wiring board failure mechanism manifested itself only after about four years of implant so that the corrective action of filling the unfilled plated-through holes was not implemented until many units had been implanted.

The overall rate of failure for Lambda series pacers has been fairly constant for the past three years, and is now about 0.09%/month for model 190A, the Lambda series model with the most implants. However, since the oldest of these pacers have been implanted for almost nine years, this rate will be increasing as batteries begin to deplete because of normal wear-out.

While Cordis did not submit 510(k) notifications for the change requiring the filling of plated-through holes or for the change in the battery burn-in process, Cordis did inform the FDA about these problems with copies of two Technical Memoranda and five Product Updates which were sent to the FDA at the time each was provided to physicians. Also, Cordis discussed these failure modes with Mr. Dahms, as summarized in a December 9, 1982 letter.

Cordis believes that the general mailing of two Technical Memoranda on early battery depletions and five Product Updates on early battery depletion and printed wiring board failures to all 15,000 physicians on Cordis mailing list has adequately notified implanting and monitoring physicians of these problems since these pacers have met their original predictions for reliability. Those predictions were based on expected failure rates for the various components. While failure rates have been higher than expected for batteries and printed wiring boards, these were offset by the lower than expected failure rate for hybrid circuits, and the overall performance of these pacers has met predictions.

Cordis plans to publish a new Product Update for all pacer models in October. Since the oldest Lambda Series pacers are approaching nine years of implant, the begining of normal wear-out depletions and the resultant decrease in reliability of old Lambda series pacers will be discussed in the Update. Cordis believes that a notification concerning Lambda and Theta series pacers is not warranted because their achieved reliabilities have met the predictions, physicians have been kept informed by the Cordis publications and the Lambda pacers are now, after almost nine years, entering the battery wear-out phase, which would in any event require more frequent monitoring. (See Figures 1, 2, 3)

3. "Charity" Pacers

Cordis has discontinued the donation of pacers that were slightly out-of-specification or out-of-date and will retrieve any that have not been implanted. These units were donated as a public service at the request of physicians who had patients who needed pacers but had no funds or insurance to cover the cost. At the time of shipment, Cordis notified each physician about the specific out-of-specification condition of each pacer. Incidentally, Cordis did not benefit from this practice by treating these units as "charitable contributions" for tax purposes.

Cordis believes that the practice of providing functional but slightly out-of-specification pacers for indigent patients is desirable provided that the discrepancy is small and that the physician is informed about the out-of-specification condition of each pacer. However, Cordis understands FDA's position and will not resume such donations until it has developed a procedure that is acceptable to the FDA. Also, Cordis will notify all monitoring physicians, other than the physicians who originally received them, about the out-of-specification status of each implanted unit.

4. Programmers, Models 255A III and 256 IAP

Each programmer is shipped with general instructions for use, but the specific instructions for programming model 233F and 415A pacers with programmers having different software revisions are included with each pacer. In addition, the revision level identification is included in each software revision so that the user can call up and read the revision level on the programmer display and refer to the correct matching instructions.

Model 233F and 415A pacers are equipped with a "back-up" pacing mode in which the pacers pace VOO at a rate of 52.5 ppm at end-of-life or if a component fails. However, electrocautery, defibrillation or similar procedures can cause these pacers to go into this "back-up" mode inappropriately. The original pacer-specific programmer instructions explained how to turn off the "back-up" mode in model 255A III and 256 IAP programmers with software revision levels 3004 and X.09, and that the "Stat Set" in these units will not turn-off the "back-up" mode.

Software revisions 3005 and 3006 for programmer Model 255A enable the user to turn off the back-up mode with the "Stat-Set" button in addition to the procedure used in the prior software revision. When software revision 3005 was introduced, the pacer-specific programming instructions were revised to include the use of "Stat-Set" as an additional means to turn-off the "back-up" mode. However, since Model 255A programmers with software revision 3004 and model 256 IAP programmers with software revision X.09 were still being used by physicians, a labeling addendum was included with each pacer to warn that the "back-up" mode could not be turned off by entering "Stat-Set" in these programmers. Therefore, the programmer instructions being distributed provide information that matches all of the software revisions that have been distributed, and there is no confusion on how to program model 233F and 415A pacers if the instructions are followed.

The only unnecessary explantations occurred during the early part of the clinical investigation because the "back-up" mode occurred inappropriately, and the physician did not turn off the "back-up" mode and put the pacer into a normal pacing mode. Cordis knows of no instance in which explantation occurred due to a mismatch of instructions and software. As explained above, appropriate instructions were provided to the physicians at all times.

The "back-up" mode is a feature of the following pacer models: 415A, 418A, 233F, G, GL, GR, and 402A. All of these pacers are shipped with instructions that match all available programmer software revisions, and there is no problem in matching the instructions to the programmer software revision level being used.

The FDA approved the PMA application for the model 415A pacer which included the pacer-specific programming instructions for the model 255A programmer with software revisions "3005 and higher". However, Cordis will submit PMA supplements for software revisions 3005 and each future revision of software for model 255A III programmer as requested. No further software revisions are planned for model 256 IAP, since this model has been obsoleted. Cordis does not believe that either notification of physicians and hospitals or stopping distribution of the programmers is warranted since there is no "mismatch" between labeling and programmer software revisions.

5. Gemini 415A Pacer

FDA was not immediately notified of the "cross-talk" phenomenon because the FDA approved Instructions for Use for Model 415A pacers addressed the problem under the heading of "Inappropriate Sensing and Stimulation at High Output Settings." Although the term "cross-talk" was not used, the description of the phenomenon and the instructions for restoring normal pacing are appropriate. In fact, nine of the ten instances of "cross-talk" encountered in the clinical investigation of 1028 model 415A pacers were completely corrected by following the instructions for correction of inappropriate sensing. Replacement of the ventricular lead was effective in the one instance where reprogramming was ineffective in correcting the situation.

"Cross-talk" was not discussed in the June 1983 IDE Progress Report because at that time the problem had not yet been recognized. Cordis does not understand why the FDA considers the discussion on cross-talk in the Final IDE Report to be inadequate. The discussion thoroughly discusses the phenomenon, the roles of the anodal rings and competitive leads in exacerbating the problem, the incidence of the problem and the means used to correct the problem. Thus, since each clinical investigator and IRB Chairman has received a copy of this final report, Cordis believes that they have been adequately notified and that no "Safety Alert" is required.

6. Multicor "Mini-Gamma" Model 340A Pacer with Polypropylene Protected Battery Feedthrough

Cordis did not file a 510(k) notification for model 340A because it believed that reduction in size of the battery and pacer case could not affect safety or effectiveness relative to the model-337A from which it was derived and which had an approved 510(k) notification. The reliability of model 340A has been excellent with a cumulative survival of 99.6% at 38 months.

Cordis understands that the FDA has adopted a new, more stringent posture regarding 510(k) notifications and will discontinue distribution of model 340A pacers until a 510(k) notification is approved. However, these small pacers are very desirable for use in children and frail elderly patients. Cordis hopes that some procedure can be arranged to obtain FDA approval to supply units to physicians for such patients while the 510(k) notification is in the submission and approval cycle.

7. All Pacers with Polypropylene Protected Battery Feedthrough

On June 22, 1984, Cordis wrote to Mr. Trujillo to summarize the data which verified the effectiveness of the polypropylene feedthrough protection and to explain why Cordis did not stop shipment of pacers with polypropylene battery feedthrough protection. The data clearly showed the effectiveness of polypropylene in protecting against early battery depletions. Since that time, Cordis has provided monthly updates of that information which have continued to confirm the effectiveness of the polypropylene feedthrough protection.

The 510(k) notification concerning polypropylene protection was submitted on April 5, 1984, and at the request of FDA, Cordis submitted a summary on June 5, 1984. On August 20, Cordis received a letter from Mr. Chissler requesting unspecified additional information. Further inquiry on August 22 established that the requested additional information had already been provided when Cordis sent copy of the August 13 monthly Gamma update to Mr. Dahms on August 15, 1984.

As requested, Cordis is providing the cumulative survival for Gamma pacers with polypropylene protected and unprotected cells at 12, 24 and 36 months (See Figures 4, 5) and will continue to provide monthly reports to the FDA.

Cordis recognizes that FDA now requires 510(k) notifications for changes which in the past were judged by Cordis not to require notifications. In 1980, Cordis did not submit a 510(k) notification for the addition of the polypropylene feedthrough protector because it considered feedthrough glass corrosion, which the change was intended to prevent, to be only a potential mechanical problem. About two years later, Cordis learned that the change greatly improved Gamma pacer reliability by also preventing early battery depletion. In view of the continuing excellent reliability of Gamma pacers with the polypropylene feedthrough protector, Cordis questions the appropriateness of FDA's request to stop shipment of these pacers on the basis that the retrospective 510(k) notification has not yet received FDA concurrence more than five months after its submission.

8. Torque Control Balloon Catheters, Catalog Nos. 530-712, -713, -722, -723, -812, -813, -822, -823, and -824

Cordis disagrees that there is a potential problem of separation of the tip from the catheter body due to bonding failure. There have been no failures in the use of approximately 7500 units of the above catalog items. The only failure occurred during the use of a custom torque-control balloon catheter with a complex tip shape made on special order for a specific physician.

After receiving the report of tip failure, Cordis audited the inventory of torque-control balloon catheters by subjecting samples to a destructive pull-test. All samples met the minimum specification of 7 pounds.

The hooked probe was substituted for the straight probe based on the assumption that it would be more effective in detecting voids in the fuse joint. However, use of the hooked probe commenced after a three month hiatus in torque control balloon catheter production. This start-up situation contributed to the increase in reject rate noted when the change to the hooked probe was made. Thirty-five hooked probe rejects were tested and all passed the destructive pull-test with values from 10.5 to 12.4 pounds proving that there is no correlation between the hooked probe test and the security of the tip-to-body bond.

Cordis urges the FDA to reconsider its request to stop marketing these catheters because there have been no failures reported for these catalog items, the catheters in stock have passed a rigorous destructive pull-test audit, and the increase in rejects after implementation of the hooked probe test has been determined not to be due to more effective detection of defective tip-to-body bonds.

Cordis did not submit a 510(k) notification for the hooked probe test because the change could not affect safety or effectiveness. In view of the above discussion, Cordis hopes that the FDA also will withdraw its request for a 510(k) Notification. The method for preventing failures has been discussed with the Investigators; it relies on good control of the tip fusing process. The absence of additional failures verifies the effectiveness of the controls used by Cordis.

9. Orthocor II, 284A Antitachycardia Pacer

Cordis reported in IDE G840004 the results of all animal tests performed in accordance with a protocol designed to verify that the model 284A pacer functions in vivo according to its specifications, is safe and functions predictably with extreme parameter combinations and to identify any undesirable interactions between the pacer and the heart. Although these animal tests followed most of the requirements of the GLP regulations, they did not adhere strictly to all of the requirements, as explained in the IDE.

The animal testing cited in the IDE was done on four dogs in accordance with the protocol described above. None died during or after the tests as a consequence of the testing. Three of the four dogs were sacrificed deliberately because the surgery to insert leads and pacers was not aseptic. The fourth dog was not sacrificed because its ventricular lead had been implanted aseptically eight months earlier, and it was to be used for additional tests unrelated to the model 284 pacer.

Three additional animal experiments were performed on one dog each in December, 1983, at Massachusetts General Hospital; in January, 1984, at Miami Heart Institute; and in February, 1984, at Dr. Bild's Animal Hospital in Miami. These experiments in surgically infarcted dogs constituted an attempt to create a good animal model to demonstrate pacer response to spontaneous tachycardias. The animals were infarcted by ligation of coronary arteries and tying off a segment of the heart near the apex, which made them prone to tachycardia and fibrillation. Two of the animals were sacrificed on conclusion of the exploratory experiments and one was sacrificed later. None of the deaths resulted from the experiments with model 284A pacers. The Cordis Research Department issued a formal report in mid-February, 1984 on these particular tests.

In retrospect, Cordis believes the report of the one test prformed prior to submission of the IDE should have been included with the submission and the reports of the other two submitted later. These reports will be submitted as a supplement to the IDE. It is Cordis opinion that they do not affect the conclusion that the Orthocor II pacer should proceed into clinical investigation.

After reviewing the observations on the electromagnetic interference testing of Orthocor II, Cordis decided to repeat the testing. This was performed on two Model 284A pacers at the Martin Marietta Aerospace facility following Cordis specification 9S10042 in all respects. Both pacers met the requirements for EMI resistance at all pulse modulation rates with no false sensing.

Cordis has exported only a few Orthocor II pacers to qualified investigators for clincial research purposes. Four units have been implanted and reports concerning the effectiveness of three of the units have been received. The results have been uniformly excellent. In all three cases, every episode of tachycardia was successfully terminated by the pacer and the need for drug therapy was eliminated.

Cordis has discontinued further export of model 284A pacers and is preparing responses to the deficiency letter and the FD 483 report relating to IDE G840004 which it believes will satisfy the requirements for reapproval of exports to the Netherlands and Venezuela and approval of the IDE. Meanwhile, in light of the information presented here, Cordis is of the view that retrieval of the few unimplanted Orthocor II pacers that were exported for investigational use is not justified.

Cordis sincerely hopes that this information and our meeting with you will resolve the issues raised in your letter and demonstrate that Cordis does not disregard, but seriously strives to meet all requirements of the Federal Food, Drug and Cosmetic Act.

Sincerely yours,

Norman R. Weldon
President

Harold Hershenson
Executive Vice President

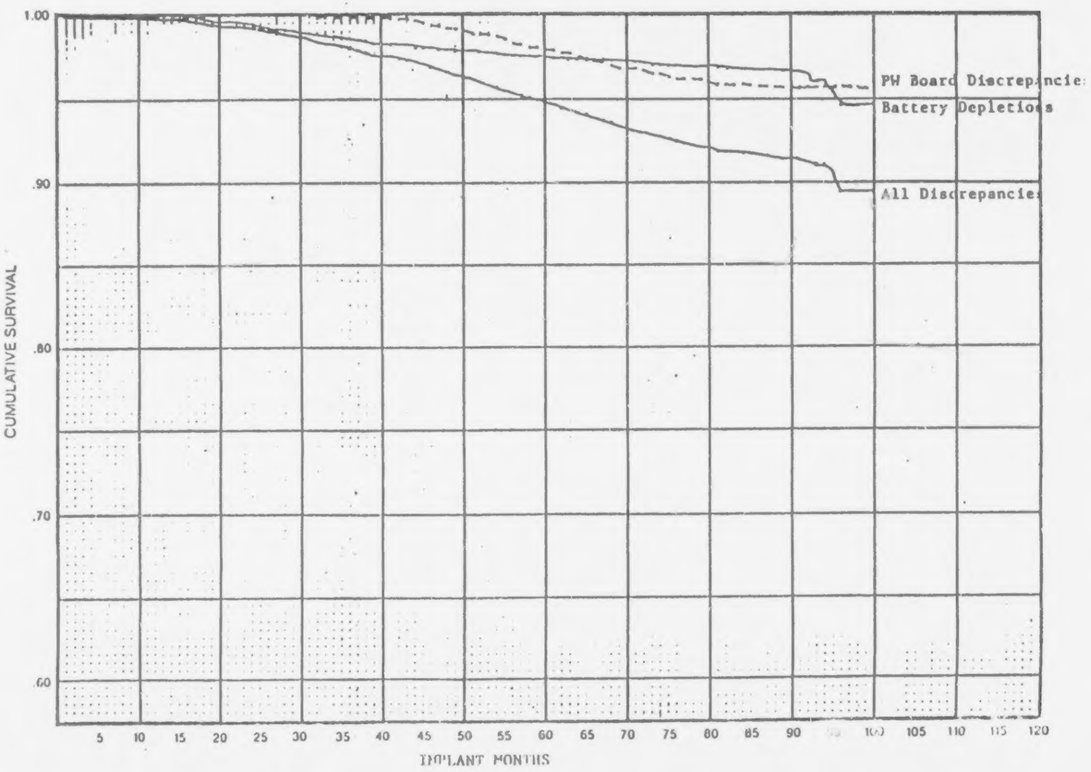
CUMULATIVE SURVIVAL OF LAMBDA AND THETA SERIES PACERS WITH POTENTIAL FOR PWB FAILURE
(AS OF AUGUST 31, 1984)

		CUMULATIVE SURVIVAL(%)				MONTHLY FAILURE RATE	
MODEL	IMPLANTS	ALL FAILURES	BATTERY DEPLETION	PWB	AT MONTH	BATTERY	PWB
188A7	3958	97.0	97.5	100.0	88	0.035%	0.000
188B7	1119	98.2	99.8	99.3	59	0.004%	0.006%
190A	21853	89.5	94.7	95.7	100	0.039%	0.045%
190E	1791	92.4	97.7	95.3	84	0.029%	0.050%
206A	4450	95.7	98.8	98.8	75	0.017%	0.001%
208A	404	94.6	100.0	96.9	70	0.000	0.006%
215A	121	98.8	100.0	98.8	57	0.000	0.019%
235A	292	100.0	100.0	100.0	61	0.000	0.000
236A	145	100.0	100.0	100.0	47	0.000	0.000
217A	6003	99.6	100.0	100.0	61	0.000	0.000
221A7	1411	96.9	100.0	97.5	70	0.000	0.036%
221B7	2567	98.7	100.0	99.0	64	0.000	0.013%
238A7,B7	723	99.7	99.9	100.0	64	0.003%	0.000
241	369	100.0	100.0	100.0	45	0.000	0.000

cordis.

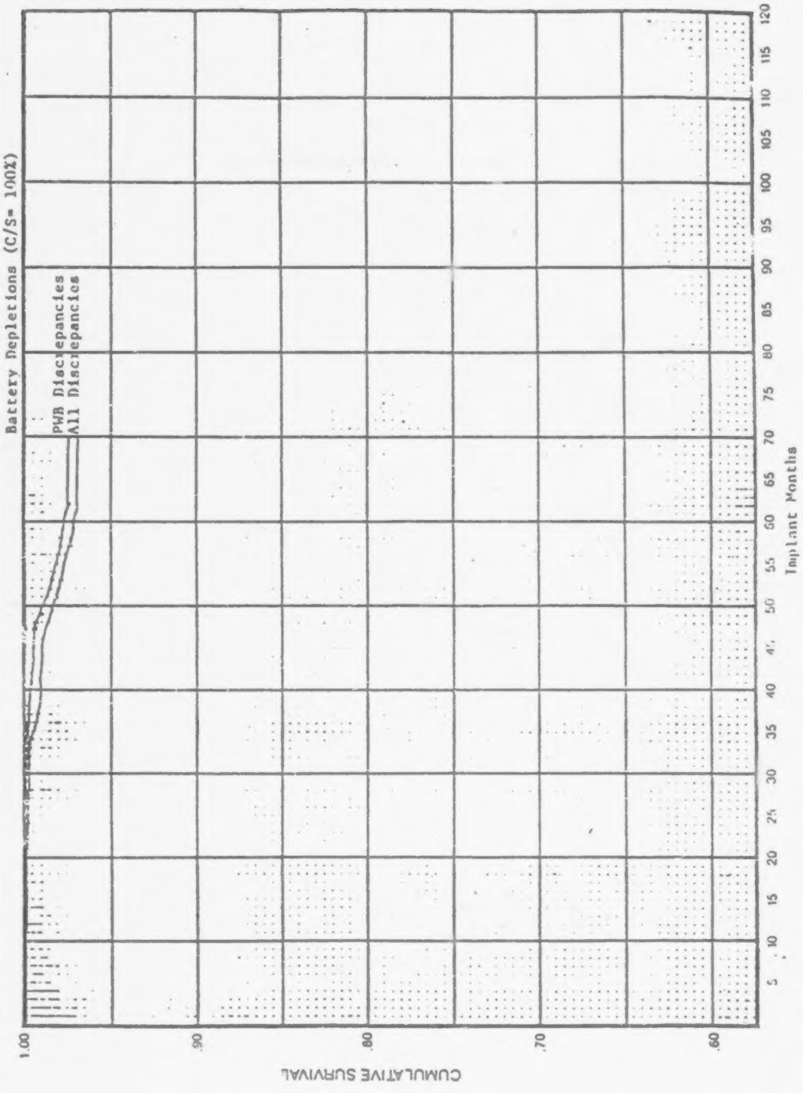
CUMULATIVE SURVIVAL

SUBJECT: Cumulative Survival of Lambda model 190A pacers as of August 31, 1984

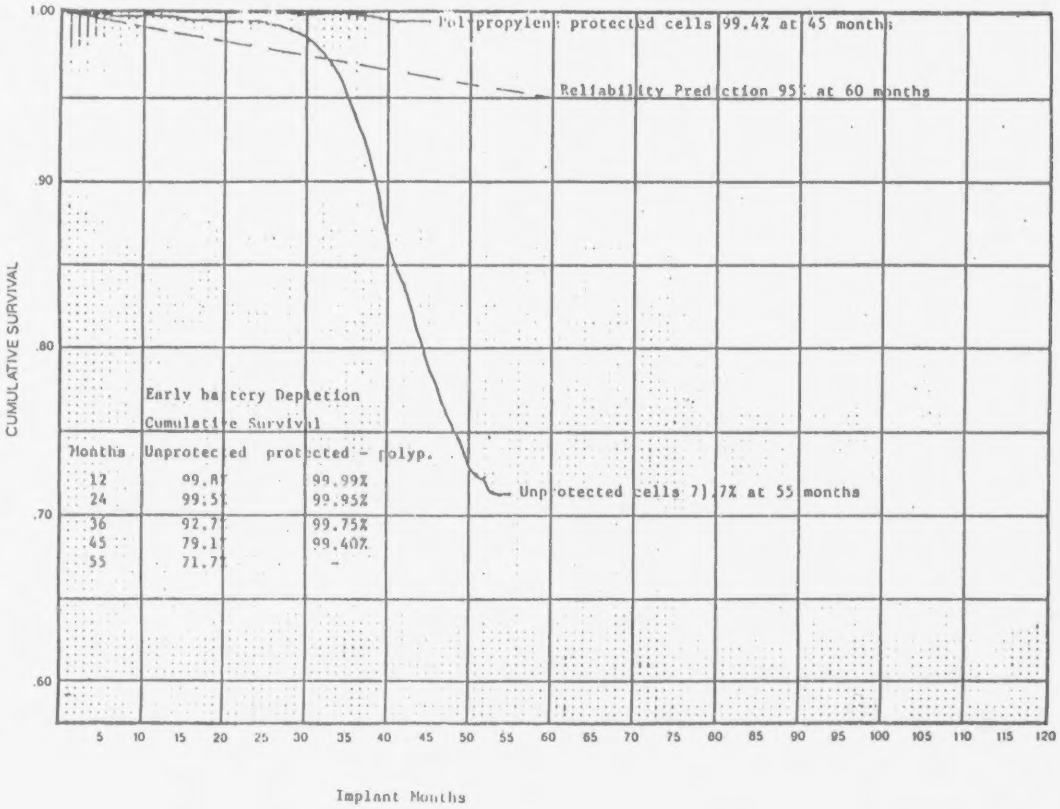


CUMULATIVE SURVIVAL

SUBJECT: Cumulative Survival of Theta 7[illegible]1A7 Pacers as of September 1, 1984



SUBJECT: Cumulative Survival of Gamma Pacers as of September 1, 1984 - Early Battery Depletions



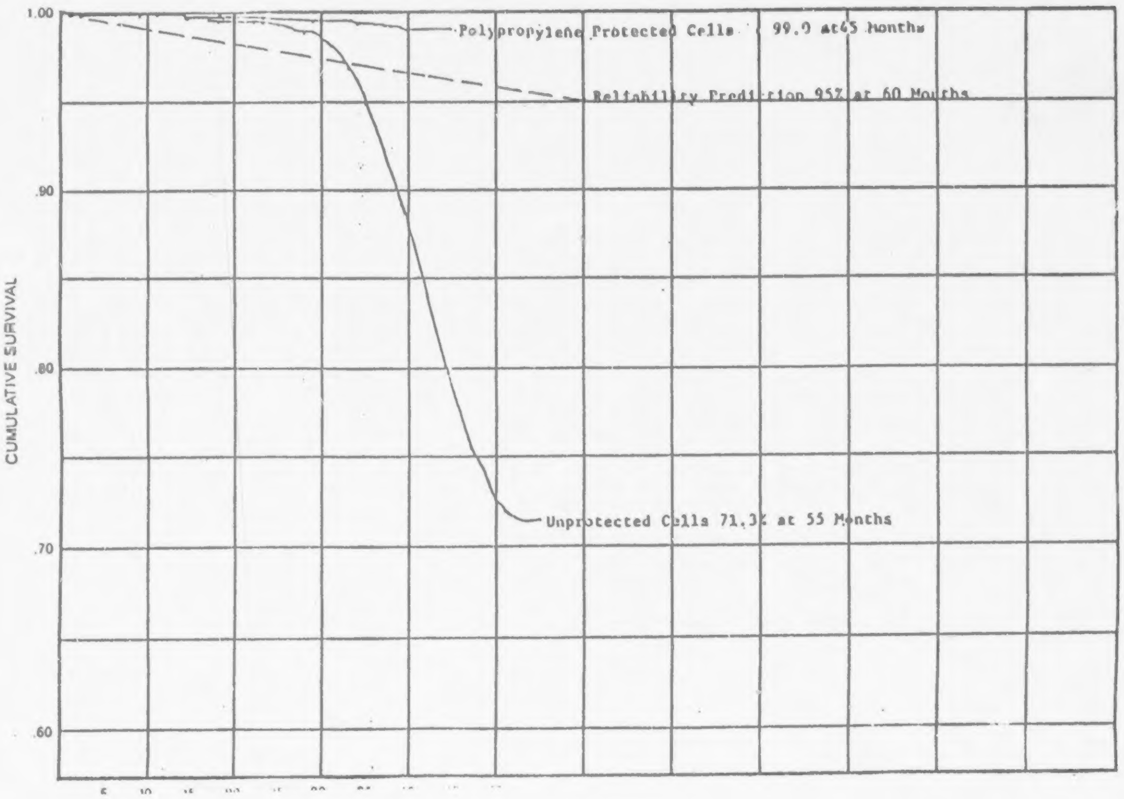
Early battery Depletion

Cumulative Survival

Months	Unprotected	protected - polyp.
12	99.8%	99.99%
24	99.5%	99.95%
36	92.7%	99.75%
45	79.1%	99.40%
55	71.7%	-

CUMULATIVE SURVIVAL

SUBJECT: Cumulative Survival of Gamma Pacers as of September 1, 1984 - All Failures



MINUTES OF MEETING

Participants: FDA Representatives

James Benson, Deputy Director, CDRH
Walt Gundaker, Director, Office of Compliance, CDRH
William Damaska, Director, DCO/OC/CDRH
Leonard Stauffer, Chief, Recall & Notification Branch, CDRH
Merv Shumate, ORA
Edward Atkins, ORL-DO
James Casey, ORL-DO/Miami RP
Fred Hooten, DCP/CDRH
Robert Skufca, OHH/CDRH
Arthur Levine, OGC
Michael Landa, OGC
Roger Schneider, OST
Glenn Rahmoeller, ODE

and

Cordis Corp. Representatives

Harold Hershenson, Cordis Corp.
Richard Morey, Kleinfeld, Kaplan, and Becker
Norman Weldon, Ph.D, President, Cordis Corp.
John Pagones, Cordis Corp.

Date: September 18, 1984

Subject: Villforth Letter of September 7, 1984, Sent to Cordis Corporation, Miami, Florida

Mr. Gundaker opened the meeting with introductions and discussed the subject letter using the main points of the letter i.e. the situations identified as serious health concerns, as a format. Each of the identified problem areas were discussed, as follows:

1. Heat Stressed Pacers

The firm's representatives discussed the problems of heat stressed circuits. They claimed heat stressing for circuits is no problem because it is a common practice to heat soak circuits. They agreed to provide FDA with a draft safety alert letter by September 21 to inform physicians of the problem because of their failure to replace batteries which were subject to the heat treatment.

2. Lambda Pacer Problem

The firm's representatives stated that the prior technical memos were adequate to inform physicians of the problem. They agreed to send all the technical memos and product updates to us by September 21 and delineate those items which specifically addressed the problem. We agreed to re-evaluate our position regarding the adequacy of the product updates after reviewing the submitted material. Mr. Benson stated that the 510(k) issue is still open for Lambda pacers.

3. "Charity" Pacers.

The firm's representatives agreed to notify U.S. Physicians, and to stop domestic and foreign distribution and to check records for additional "Charity" Pacers.

4. Pacemaker Programmer

The firm will submit all the labeling and instructional information associated with the three products to FDA by September 28 for review. They also requested an abeyance on the cessation of shipping programmers. We agreed to allow distribution while we review the submitted material. They also agreed to submit IDE's and PMA's by October 12.

5. Gemini 415 A - Crosstalk

Instructions for generic crosstalk problems were contained in final IDE reports. The firm's representatives agreed to submit a draft medical device alert by October 5.

6. Mini Gamma (used for the elderly, debilitated and children).

The firm's representatives agreed to stop shipping the Mini Gamma and to submit a 510(k). They will submit a request for interim use on a case by case basis.

7. Polypropylene Feedthrough

The firm presented data which they believe shows that the cumulative survival rate for protected feedthroughs is better than unprotected. We will complete our review of the 510(k). The firm requested permission to ship 400 pacers with polypropylene feedthroughs which are currrently in stock. We did not agree to any distribution until further evaluation of the 510(k) is completed.

8. Balloon Catheter

The firm claimed that their test was inappropriate. We withdrew our request for the cessation of marketing. We promised to inform the firm if we decided that they needed a 510(k) for the testing procedure.

9. Orthocor

The firm's representatives contended that the dogs used in their study were deliberately sacrificed. The firm is going to submit animal data to support their IDE. We agreed to reconsider their request to reinstate the permission to export upon completion of the review of data submitted.

Leonard J Stauffer

Leonard J. Stauffer

ATTENDEES CORDIS - FDA MEETING 9/18/84

NAME	Representing
Leonard Stauffer	DCO, Recall and Notification Br.
James Benson	Deputy Director, CDRH
Walt Gundaker	Director, Offfice of Compliance
Merv Shumate	ORA, FDA
Edward Atkins	ORL-DO
James Casey	ORL-DO/MIA-RP
Fred Hooten	OC, DCP, MQAB
Robert Skufca	OHH, CDRH
Arthur Levine	OGC
Michael Landa	OGC
Roger Schneider	OST
Glenn Rahmoeller	ODE
Harold Hershenson	Cordis Corporation
Richard Mo~~s~~rey	Kleinfeld, Kaplan, and Becker
Norman Weldon	Cordis Corporation
John Pagones	Cordis Corporation
Bill Damaska	DCO/OC/CDRH

Cordis Corporation
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Telephone 305-551-2000
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Cardiovascular Instrumentation

cordis.

September 20, 1984

Mr. William Damaska
Director, Division of Compliance
HFZ 320
Bureau of Medical Devices
8757 Georgia Avenue
Silver Spring, MD 20910

Dear Mr. Damaska:

The following summarizes the actions and schedules which Cordis has agreed to as the result of our September 18, 1984, meeting. Please let me know if there is any discrepancy between our summary and your own.

1. Heat Stressed Pacers

Cordis will draft the following documents concerning pacers inadvertently heated for gas analysis: 1) a letter containing a description of the problem and monitoring recommendations for all physicians monitoring these units; 2) an additional letter for physicians following any units which were also included in the Gamma notification; 3) at Dick Morey's suggestion, a "hazard analysis", using the FDA format; and 4) the percentage of units which were included in the Gamma notification. All of the above will be delivered to Mr. Damaska at the CDRH through Dick Morey on Friday, September 21, and directly to Mr. Casey in Miami.

Although the FDA left the decision to Cordis, we agreed to include all heat-stressed units in this notification whether or not the batteries have been replaced. This will probably involve about 150 units, of which about 70 do not have replaced batteries.

2. Lambda, Theta Pacers

Cordis will provide copies of the Technical Memoranda and Updates relating to these models marked to highlight discussions of the battery depletion and printed wiring board problems to Mr. Damaska and Mr. Casey. These also will be delivered by Mr. Morey on September 21. In addition, we will submit a draft of the October Update which will include a discussion of the impending end-of-life depletions in Lambda model pacers to Mr. Damaska, Mr. Rahmoeller and Mr. Casey for review and comment as soon as the draft is ready.

3. Charity Pacers

Cordis has discontinued donations of out-of-specification pacers and will notify by letter any monitoring physicians who were not the original recipients of the out-of-specification condition of the pacers they are monitoring. In addition, Cordis will identify any additional out-of-specification charity pacers not previously identified to the FDA and provide that information, along with the draft of the letter to Mr. Damaska and Mr. Casey for review and comment. The question of developing a mechanism for donating out-of-specification pacers was not resolved, but the FDA is willing to entertain recommendations.

4. Programmers

FDA will hold their stop-shipment request in abeyance until they have had an opportunity to review the following information which Cordis will provide to Mr. Damaska and Mr. Casey by September 28: 1) a simple explanation on how physicians are able to match programming instructions and programmer software revisions, and 2) an accounting of the software revision levels in programmers in the field.

In addition, Cordis will prepare and submit PMA supplements for Model 233F and 415A pacers for all of software revision levels not included in the original PMA submissions by October 12.

5. Gemini "Crosstalk"

Cordis will provide to Mr. Damaska and Mr. Casey by October 5 a draft letter to notify all M.D.'s following Gemini units with the dual anode rings about the additional potential for crosstalk in those units.

6. Mini-Gamma Pacers

Cordis has discontinued shipment of the mini-Gamma pacers until the 510(k) is submitted and approved by FDA. FDA may consider approval of shipments for individual emergency cases, but no specific agreement was reached on this point.

7. Pacers with Polypropylene Protected Battery Feedthroughs

Cordis agreed to stop shipment of all units with polypropylene feedthrough protectors until FDA approves the 510(k) submitted in April of 1984. Cordis will provide information about the number of quarantined units and their "use before dates" to Mr. Rahmoeller, Mr. Benson and Mr. Britain to encourage quick approval.

Cordis also agreed to continue the monthly report to Mr. Casey concerning the reliability of the polypropylene protected batteries.

8. Torque-Controlled Balloon Catheters

The FDA withdrew their request to stop shipments of this product, and Mr. Gundaker will decide whether or not a 510(k) is required for the change to a hook probe test.

9. Orthocor II

As requested, Cordis has stopped further export of Orthocor II pacers until the response to the FD483 report relative to the Orthocor IDE is completed and sent to Mr. Trujillo. In addition, Cordis must respond to the deficiency letter regarding the IDE by October 20, 1984. However, Doctor Weldon will request, by letter to Mr. Damaska, renewal of the export license for investigational use only.

Sincerely yours,

Harold Hershenson
Executive Vice President

HH:mdb
cc:
James Benson
Richard S. Morey
John N. Pagones
Norman R. Weldon

HEALTH HAZARD EVALUATION

DATE: September 20, 1984

1. PRODUCT: Heat-Stressed Pacers - 179 units distributed between 1980 and 1983 - 217A, 221B7, 233F/G, 237A, 308A, 333B7/D7, 334A, 336A/B, 337A, 402A/B, 415A
2. MANUFACTURER OR FIRM: Cordis Corporation, Miami, Florida
3. PRODUCT DESCRIPTION AND USAGE: Cardiac Pulse Generators
4. REPORTED PROBLEM, INCIDENT, DEFECT, DEFICIENCY, MALFUNCTION OR FAILURE: Inadvertent exposure for one to 65 hours to temperatures up to 127°C, which exceeded specified temperatures for normal processing. Normally the maximum temperatures to which the hybrid circuit, the pacer circuit assembly and the battery are exposed are 125°C, 95°C and 54°C, respectively.
5. NUMBER OF ADVERSE EFFECTS, DISEASE, INJURIES OR DEATHS THAT HAVE OCCURRED FROM USE OF THE PRODUCT: None
6. TECHNICAL EVALUATION: Product salvaged and re-used inappropriately after high temperature exposure for gas analysis. Test exposure of batteries to 125°C for 15 hours revealed no anomalies or loss of electrical capacity. Implanted pacers have achieved a cumulative survival of 92.4% on 37 months. There have been no component failures other than twelve early battery depletions, eleven of which were due to unprotected battery feedthroughs and subject to a Class I notification and only one was related to this high temperature exposure.
7. MEDICAL EVALUATION: Remote possibility of no output failure which would be a hazard to pacer-dependent patients.
8. IDENTIFIED HAZARD OR RISK RESULTING FROM USE OR EXPOSURE TO THE PRODUCT: There has been only one early battery depletion which appears to be related to excessive heat and there was no associated adverse clinical consequence. Therefore, the only risk arises from latent, undetected heat-induced defects which may cause pacer malfunction with time.

9. CLINICAL CONSEQUENCES THAT MAY RESULT FROM THE HAZARD: There is a potential adverse clinical consequence if a heat-stressed pacer implanted in a pacer-dependent patient suddenly fails in a no-output mode. However, with monthly monitoring and consideration or replacement in pacer-dependent patients as recommended by Cordis, there should be no clinical consequence except that related to the replacement surgery.

10. CONDITIONS OR FACTORS WHICH MAY CONTRIBUTE TO OR REDUCE THE HAZARD OR RISK: The Cordis Safety Alert should reduce the hazard by recommending monthly monitoring and consideration of prophylactic replacement in pacer-dependent patients. Further, the batteries, which are the components most likely to be heat-sensitive, were replaced in 109 of the 179 heat-stressed units which were distributed. Also, 35 of the 179 units were included in the Cordis Class I Notification concerning Gamma pacers with a potential for early battery depletions with the same monitoring recommendations as the Safety Alert relating to heat-stressed pacers.

11. PROBABILITY OF ADVERSE HEALTH CONSEQUENCES RESULTING FROM USE OR EXPOSURE TO THE PRODUCT: Remote

12. SUMMARY: There has been only one failure in the 179 units distributed that could be attributed to excessive heating and there was no associated adverse clinical consequence. The probability of adverse health consequences is remote, particularly if the recommendations in the Cordis Safety Alert are followed.

PREPARED BY: Harold Hershenson
Harold Hershenson,
Executive Vice President

JN Pagones
John N. Pagones
Vice President
Corporate Product Assurance

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coral

ADDENDUM TO THE HEALTH HAZARD EVALUATION OF SEPTEMBER 21, 1984

29

Further review of available data leads to the conclusion that the only failed heat-stressed pacer, 233F-9549, which failed due to melting of the battery separators, was exposed to a higher temperature than the rest of the heat-stressed pacers and thus the probability of similar failures of heat-stressed pacers is small:

a. Pacer 233F-9549 failed after 3.5 months of implant. The other heat-stressed pacers have been operating for up to 51 months of implant (see attached histogram). If any other units had been heated to a temperature high enough to melt the battery separator, other failures would be expected to have occurred since this mechanism would lead to a short implant life. Therefore, it appears that the high temperature exposure of Pacer 233F-9549 was unique.

b. Eleven Gamma batteries in heat-stressed pacers failed due to electrolyte attack on unprotected feedthroughs and were cut open for analysis. None showed evidence of separator melting of the type seen in the battery from Pacer 233F-9549.

c. The temperature necessary to melt the Pellon battery separator was determined in the laboratory to be about 140° C. Since the ovens and heating blocks used in the gas analyses were set to 115° C., the heating which caused melting of the battery separator in Pacer 233F-9549 was probably due to a unique high temperature excursion of either an oven or a heating block.

d. The gas composition in Pacer 233F-9549 was uniquely high in methane, 10.4 mole %. The

---

next highest concentration of methane was 2.7 mole % and most of the other heat-stressed pacers had less than 1 mole %. The only conceivable source for methane in a pacer is heat degradation of organic materials in the pacer. Since Pacer 233F-9549 had much more methane than any other heat-stressed pacer, Cordis concludes that it was heated to a higher temperature than any of the other heat-stressed pacers.

FYI in failure 7. the patients expired

Only one other heat-stressed pacer, 233F-[illegible]0160, with more than 1 mole % of methane was released and implanted without replacing the battery. This unit was implanted September 9, 1983, and is still operating satisfactorily.

[illegible] notified 19 were notified,

e. Cordis Europa in Holland distributed 182 pacers which had been subjected to gas analysis. Most of these units were analyzed at 115° C. and the batteries had been replaced during rework in all except 19 units. There have been no failures of any kind in this group, and 158 remain implanted.

This additional information supports the summary of the September 21, 1984, Health Hazard Evaluation which states that the probability of serious adverse health consequences is remote. Thus, the Cordis Notification on Heat-Stressed Pacers should be classified as a Class II, not a Class I, Recall.

CORDIS CORPORATION

By: Harold Hershenson
Harold Hershenson
Executive Vice President

HH:mdb
Attach.

October 23, 1984

. OF OCTOBER 18, 1984

MONTHS	PACERS	
1	1	*
2	1	*
3	4	****
4	1	*
5	1	*
6	1	*
7	2	**
8	8	********
9	3	***
10	3	***
11	3	***
12	5	*****
13	3	***
14	5	*****
15	3	***
16	2	**
17	5	*****
18	6	******
19	7	*******
20	5	*****
21	3	***
22	3	***
23	2	**
24	5	*****
25	6	******
26	1	*
27	3	***
28	1	*
29	3	***
30	2	**
31	0	
32	2	**
33	3	***
34	2	**
35	4	****
36	1	*
37	2	**
38	6	******
39	1	*
40		
41	1	*
42	3	***
43	1	*
44	1	*
45	4	****
46	2	**
47	2	**
48	1	*
49	1	*
50	1	*
51	1	*
TOTAL	137	

SUMMARY

TOTAL HEAT STRESS PACERS		179
NOT IMPLANTED	15	
TOTAL IMPLANTS		164
EXPLANTS	27	
NET STILL IMPLANTED		137

SIGNED:

DATE: 10.23.84

Date: October 16, 1984

To: H. Hershenson, Executive Vice President

From: D. C. MacGregor, M.D., Vice President, Medical Research

Subject: Health Hazard Evaluation of Heat-stressed Pacers

I am writing in response to your request for a professional opinion regarding the Health Hazard Evaluation which was submitted to the FDA on 179 heat-stressed pacers distributed between 1980 and 1983.

The Health Hazard Evaluation clearly states the problem. As a physician, I consider this to be minor in that only one premature battery depletion has resulted to date and the data suggest that further failures are unlikely. It, therefore, is my opinion that the possibility of these pacers causing serious adverse health consequences is very remote. The situation barely warrants being classified as a Class II recall.

At one point during my ten years' experience with over 3,000 pacer implants, I examined the morbidity associated with 191 unpredicted pacer failures which occurred over a four year period (see reference). Of the 191 patients, 145 (76%) were totally asymptomatic, 35 (18%) had minor symptoms and only 11 (6%) had sufficient symptoms to require a temporary pacing lead, this being the relatively pacer-dependent group. There were no deaths between the time the pacer failure was identified and its subsequent replacement.

It is generally quite sufficient for physicians to monitor these patients monthly, either by office visits or by telephone monitoring. I also agree that in the rare instances of total pacer dependency, prophylactic replacement should be performed. These patients can easily be identified at the time of surgery or postoperatively by pacer programming and/or overdrive suppression.

With this experience as background, I feel confident that the problem under discussion can be fully addressed in a Class II recall. I also think that it would be unreasonable for the FDA to use a Class I designation because of the needless morbidity, and possibly mortality, which would result from less experienced physicians over-reacting to the situation, not to mention the needless anxiety which the affected patients would suffer.

continued...

As requested, I am also enclosing a copy of my curriculum vitae for your reference. Please feel free to contact me for additional information if required.

Reference: MacGregor, D.C., Noble, E.J., Morrow, J.D., Scully, H.E., Covvey, H.D., and Goldman, B.S.: Management of a Pacemaker Recall, Journal of Thoracic and Cardiovascular Surgery 74:657-667, 1977.

DCM/nf
Enclosure (Curriculum Vitae)

cc: J. N. Pagones, Vice President, Corporate Product Assurance

John

VINCENT A. KLEINFELD
ALAN H. KAPLAN
ROBERT H. BECKER
THOMAS O. HENTELEFF
RICHARD S. MOREY
PETER O. SAFIR
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TELECOPIER
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October 18, 1984

Mr. John H. Samalik (HFK-113)
Center for Devices and
Radiological Health
Food and Drug Administration
8757 Georgia Avenue
Room 1248
Silver Spring, MD 20910

Dear Mr. Samalik:

As you requested, this will provide an agenda for our meeting with the Health Hazard Committee on Wednesday, October 24, 1984 at 10:00 a.m. As you know, the purpose of the meeting is for Cordis to present its views as to why its recent notification on heat stressed pacers should not be classified as a class I recall.

The company plans to make a brief technical presentation explaining the nature of the problem involved with the heat stressed pacers and presenting data on the failures which have occurred and the likelihood that further failures will occur. This will be done by Harold Hershenson, Executive Vice President of Cordis.

We also plan to present to the Committee a written evaluation of the medical implications of this situation by Dr. D.C. McGregor, Vice President of Medical Research, Cordis Corporation. In addition, an outside medical consultant, Dr. Ross Fletcher, will make a presentation to the committee on the medical implications of the notification.

If you have any further questions, please let me know.

Yours very truly,

Richard S. Morey

Richard S. Morey
Counsel for Cordis Corporation

RSM/jlr

cc: Harold Hershenson

Norman R. Weldon, Ph.D, President
Cordis Corporation
10555 West Flagler Street
Miami, Florida 33172

Dear Dr. Weldon:

We have reviewed the information submitted in your firm's letters of September 20, 26, and 27, concerning the Lambda and Theta pacers with early battery depletion and printed wiring board problems; the software revisions for pacer programmers; and the out-of-specification "charity" pacers with the proposed draft letters concerning these pacers.

We have the following comments to offer:

1. Lamda and Theta Pacers With Early Battery Depletion and Printed Wiring Board Problems.

   It has been and still remains FDA's opinion that Technical Memoranda and/or Product Updates are not adequate means of notifying physicians of potentially hazardous problems with pacemakers. These notices are not adequately "flagged" and highlighted, do not state the problem, and do not declare what action the physician should take to protect the patient. In addition, there are no means provided for a response to assure that a physician read these notices.

   We are still requesting that you immediately notify all physicians of these potential problems. A draft of your proposed notification letter, and list of addresses, should be submitted for review.

2. Software Revisions for Pacer Programmers.

   We understand that all pacer-specific instructions supplied with models 233F and 415A contained an addendum which informs users of the procedure for turning off the "back-up" mode. However, we are still concerned that a number of programmers were distributed without adequate programing instructions. This could result in a patient with either of these pacers in the "back-up" mode not being reprogrammed because a physician (not the original implanter) did not have the appropriate instructions and revisions (e.g., 3005 level software). The physicians and/or hospitals that received these programmers should be immediately notified of the problem. Also, please confirm that the addendum was in fact sent to all users and not just with those pacers distributed after a certain date.

3. Out of Specification "Charity" Pacers.

We are aware of up to 33 of these pacers which were manufactured and distributed by Cordis. These include:

(a) Nineteen (19) pacers you notified us of in your letter of September 27;

(b) Ten (10) additional pacers that the "Use Before Date" was extended and sent to Dr. Littleford; and

(c) Four (4) other pacers discovered during the October 3-5, 1984 FDA inspection.

We are extremely concerned that other out-of-specification pacers have been distributed which are not being considered by Cordis. We believe that surely there must be some way that Cordis can check their files to systematically identify all "charity" pacers. Please notify us of your intention to make a complete search and when it will be completed.

Regarding the 33 pacers identified (except the one returned), it is requested that each doctor that received them, and any monitoring physician who was not the original receipient, be notified of the out-of-specification condition of each pacer.

We consider the ten pacers that had their "Use Before Date" extended and sent to Dr. Littleford, as out-of-specification. These ten pacers are to be included in your firm's letter to recipients of the pacers provided to Dr. Littleford unless your firm can provide us with copies of all test data to prove they met all specifications.

We have no objection to you using the proposed letter format for the pacer model and serial number whose out-of-specification parameter is "output current", "position sensitivity", or "30 rate" if that is the only out-of-specification parameter that each specified pacer has.

We are not, however, satisfied with the proposed letter concerning the outdated pacers. The letter fails to request return of all non-implanted pacers, and does not state what effect(s) an outdated pacer has on its performance. In addition, the statement, "...Cordis is confident that these pacers will provide excellent service..." appears to be misleading since it contradicts the precaution statement, "to assure maximum service life, pacers must be implanted before the 'use before date' on the package label", found in the pacers' Instruction for Use booklets.

We suggest redrafting another letter correcting these deficiencies.

Please respond within five (5) days as to what action you intend to take to comply with our requests and recommendations.

For your added information, a 510(K) premarket notification will not be required for the change to a hook probe test for the Torque-Controlled Balloon Catheters.

Sincerely yours,

Ann B. Holt

Walter E. Gundaker
Director
Office of Compliance
Center for Devices and
Radiological Health

cc: Mr. John H. Pagones, Vice President
Corporate Product Assurance
Cordis Corporation
10555 West Flagler Street
Miami, Florida 33172

JHS:10-4-84; Initial:LJS:10-4-84; R/D:rgc:10-4-84
REVISIONS:TM:10-10-84;JSAMALIK; R/D:bss:10/11/84
Initial:RAS:10-12-84; Comments:D. Dahms:10-15-84; ORL-DO/10-16-84;
Revised:JHS:10-16-84; R/D:rgc:10-17-84
Init:JHS:10/17/84; LJS:10/17/84; ABHolt:10/18/84
T/F:nh:10/19/84

FRANCI - #71

cc: HFZ-300 HFZ-321/3 HFR-41 HFR-4200 HFR-4575, HFC-20 (M.Schumate)

MEMORANDUM OF MEETING

Firm: Cordis Corp.
Miami, FL

Participants: CDRH

John H. Samalik, DCO, HFZ-321
Leonard J. Stauffer, DCO, HFZ-321
Donald F. Dahms, ODE, HFZ-450
Robert A. Skufca, OHP, HFZ-70
Walter L. Scott, OTA, HFZ-250
William H. Midgette, OST, HFZ-135

and

Cordis Corp.

Harold Hershenson, Exec. Vice-President
Richard Morey, Attorney, Kleinfeld, Kaplen & Becker
Ross Fletcher, M.D., V.A. Medical, Washington, D.C.

Date: October 23, 1984

Subject: Theta and Gamma Series Pacemakers (Heat-Stressed)

This meeting was requested by Mr. Morey to discuss the potential classification of Cordis' action on the subject pacers.

In addition to presenting and reading the attached documents, Mr. Hershenson promised to provide whatever information Cordis has on file on the seven patients that expired (firm's memo dated August 31, 1984).

Dr. Fletcher indicted that based on the information he has reviewed, he considered the present problem as a minor one, but worth watching.

The meeting was concluded with an agreement that the Center would reevaluate its own and the firm's health hazard evaluations.

John H. Samalik

Attachments

JS:11-13-84; RD:BS:11-13-84; Initial:LJS:11-16-84; F/C:RR:11-20-84
cc: All CDRH Attendees HFA-224 HFZ-321/3 HFO-510 HFR-4200(ORL-DO)
HFR-4575(MIA-RP)

VINCENT A. KLEINFELD
ALAN H. KAPLAN
ROBERT H. BECKER
THOMAS O. HENTELEFF
RICHARD S. MOREY
PETER O. SAFIR
NANCY SINGER
KINSEY S. REAGAN
PETER R. MATHERS
DAVID E. KAPLAN

LAW OFFICES
KLEINFELD, KAPLAN AND BECKER
1140 NINETEENTH STREET, N. W.
WASHINGTON, D. C. 20036

TELEPHONE
(202) 223-8120

TELECOPIER
(202) 223-5619

October 31, 1984

Mr. William H. Damaska (HFK-110)
Food and Drug Administration
8757 Georgia Avenue
Room 1248
Silver Spring, MD 20910

Dear Mr. Damaska:

Although I understand from our telephone conversation today that a further Cordis Product Update is not considered by the agency personnel reviewing this matter to be adequate to notify physicians of the defects in Lambda and Theta Series pacers, I am sending you a copy of the completed Product Update for your records.

I am advised that Cordis nonetheless will promulgate this Product Update to the medical profession in line with its continuing commitment to publish such updates. It will be sent to all physicians on Cordis' mailing list as soon as the printing, mailing, etc. can be accomplished.

Cordis continues to believe that this update provides adequate information to the medical community in light of the following factors:

1. The general knowledge about the Lambda and Theta defects prevalent in the medical community based on information received from Cordis in the form of prior technical memoranda and product updates.

2. The fact that the Lambda and Theta defects continue to occur at such a low rate that the Lambda and Theta Series pacers meet their predicted reliabilities except for one model which is only .004 below its predicted reliability of .906 at 101 months.

3. The lack of any new information concerning the Lambda and Theta defects or the rate at which they occur beyond what has previously been published to the medical community by Cordis.

We also point out that FDA has been aware of these Lambda and Theta defects for three years. [We see no basis for the agency now considering this situation to require a notification in the absence of new information suggesting it is more serious or occurs at a higher rate than previously reported.] The issuance of a notification under these circumstances raises the possibility of confusing the medical profession into thinking erroneously that there is a new and different problem with Lambda and Theta Series pacers than that with which they are already familiar. In addition, the value of periodic product updates, which Mr. Gundaker recognized during our meeting on October 24, 1984, is severely undercut if they are not accepted by FDA as a means of communicating some adverse as well as favorable product information to the medical community.

Finally, the recently promulgated medical device reporting regulations recognize the principle that is not necessary to report defects described in the product labeling occurring at no higher frequency than the frequency indicated in the labeling. Since the Lambda and Theta Series pacers essentially meet the reliabilities predicted in their labeling, the defects involved here (which result in the same type of no output failures predicted in the labeling) certainly do not involve a situation which should be announced to the medical community as a new and alarming development. Instead, their regular reporting within the context of product updates should be considered adequate and appropriate.

For all these reasons, Cordis continues to believe that the information provided to the medical community in the enclosed Product Update and in prior updates and technical memoranda is adequate, and that no specific notification on the Lambda and Theta Series pacers is necessary.

I look forward to hearing from you on this matter after you have consulted further with Mr. Gundaker.

Yours very truly,

Richard S. Morey
Counsel for Cordis Corporation

RSM/jlr

Enclosure

cordis®

Product Update

NUMBER 17 OCTOBER, 1984

IMPORTANT! PACER MONITORING INFORMATION

This update provides current achieved reliability data for use by monitoring physicians in the management of patients with Cordis pacers. It also contains recommendations for any special patient management actions which may be indicated for malfunctions reported for particular models of Cordis pacers.

The achieved reliability of each model has been calculated by the standard cumulative survival method from the data in the worldwide Cordis pacer registry. The achieved reliability for each model of pacer has been tabulated, along with the predicted reliability published in the labeling for the model, adjusted for the time achieved by the oldest implants.

LAMBDA SERIES PACERS

All models of the Lambda Series pacers have met or exceeded their predicted reliability except for Model 190A which is 0.004 below its prediction of 0.906 at 101 months. However, half of the total malfunctions of Model 190A and 190E units were due to printed wiring board defects which have resulted in 0.035% intermittent or sudden no output failures per implant month in these models. Cordis, therefore, recommends that monitoring physicians consider prophylactic replacement of Model 190A and 190E in pacer-dependent patients after three years of implant.

The oldest implants of Models 188A/B, 190A and 190E have been in service more than seven years and should be routinely monitored for normal end-of-life battery depletion. These impending depletions are readily detected by a rate decrease of two or more beats per minute. The pacers continue to operate for several months at the lower rate plateau, providing ample time for routine pacer replacement.

COMPARISON OF PREDICTED AND ACHIEVED RELIABILITY FOR LAMBDA SERIES PACERS

Model	Average Malfunction Rate %/Month	Predicted Reliability* Best Estimate	Lower Bound	Achieved Reliability**	At Month
188A, B	0.032	0.963	0.916	.977	89
190A	0.097	0.958	0.906	.902	101
190E	0.090	0.965	0.920	.922	85
190F	0.009	0.972	0.936	.994	67
206	0.029	0.969	0.914	.957	76
208	0.038	0.971	0.920	.956	71
215	0.022	0.975	0.932	.988	60
235	0.000	0.974	0.930	1.000	62
236	0.000	0.978	0.939	1.000	53

* Adjusted for time.

** Calculated by the cumulative survival method from the Cordis Pacer Registry as of 9/30/84.

THETA SERIES

All models of the Theta Series have achieved reliabilities which exceeded their predicted reliabilities. However, about 70% of the malfunctions of Models 221A7 and 221B7 were due to printed wiring board defects which have resulted in 0.024% intermittent or sudden no output failures per implant month in these models. Cordis, therefore, recommends that monitoring physicians consider prophylactic replacement of Model 221A7 and 221B7 units in pacer-dependent patients after 18 months of implant.

Comparison of Predicted and Achieved Reliability for Theta Series Pacers

Model	Average Malfunction Rate %/Month	Predicted Reliability*	Achieved Reliability**	At Month
217A	0.006	0.969	.997	62
221A7, B7	0.041	0.964	.968	71
232A, B	0.000	0.959	1.000	44
237A	0.006	0.949	.997	56

* Adjusted for time.

** Calculated by the cumulative survival method from the Cordis Pacer Registry as of 9/30/84.

GAMMA SERIES

As discussed in the April, 1984, Product Update, Gamma batteries manufactured prior to November, 1980, have exhibited a high incidence of early depletions after 24 months of implant. Cordis distributed a December 5, 1983, Notification and an April 18, 1984, Notification Update to physicians which recommended monthly monitoring of Gamma pacers with these early batteries and consideration of prophylactic replacement in pacer-dependent patients.

All models of Gamma pacers manufactured with batteries made in November, 1980, or later have achieved reliabilities which exceed their predicted reliabilities.

Model	Average Malfunction Rate %/Month	Predicted Reliability*	Achieved Reliability**	At Month
Notification Units 333B7, 334A 336A/B, 337A 340A	0.410	0.958	.688	56
308A	0.030	0.972	.987	37
333B7/D7	0.018	0.968	.988	42
334A	0.017	0.968	.981	43
336A/B	0.026	0.968	.983	43
337A	0.013	0.965	.992	46
340A	0.032	0.962	.983	39
402A/B/C	0.017	0.986	.998	19

* Adjusted for time.

** Calculated by the cumulative survival method from the Cordis Pacer Registry as of 9/30/84.

PHYSIOLOGIC PACERS

All models of the Sequicor and Gemini Series of physiologic pacers have achieved reliabilities which exceed their predicted reliabilities.

The theoretical battery service life for Models 233D and 233E pacers is 24 months because of the relatively high current drain of their circuits. As recommended in the instruction manuals for these models, they should be monitored for normal battery depletion after 18 months of implant. As expected, battery depletions have occurred after an average of 24.1 months. However, the achieved reliability of these models, aside from these normal battery depletions, exceeds the prediction based on expected random failures, as indicated in the table below.

		Predicted Reliability*			
Model	Average Malfunction Rate %/Month	Best Estimate	Lower Bound	Achieved** Reliability	At Month
233D/E	0.730	0.147	0.000	.583	35
233D/E***	0.063	0.977	0.969	.982	35
233F	0.019	0.997	0.984	.997	23
233G	0.035	0.998	0.991	.997	14
415A	0.031	0.996	0.982	.994	27
418A	0.000	0.999	0.996	1.000	6

* Adjusted for time.
** Calculated by cumulative survival method.
*** Calculated without normal battery depletions.

[illegible]
Miami, FL 33102-5700 U.S.A.
Telephone 305-551-2000
Telex 051112

November 20, 1984

Mr. Walter Gundaker, Director
Office of Compliance (HFZ-300)
Center for Devices and Radiological Health
8757 Georgia Avenue
Silver Spring, MD 20910

Reference: 1. Letter of September 27, 1984 from Pagones to Damaska
2. Letter of October 22, 1984 to Weldon from Gundaker (Holt)
3. Meeting on October 24, 1984 between Hershenson and Gundaker

Dear Mr. Gundaker:

At the above-referenced meeting, Cordis provided information concerning its position on the three topics cited in your letter to Dr. Weldon (Reference 2, above). This letter and attachments constitute our re-proposal on "Charity" pacers in light of concerns expressed in your letter of October 22.

Cordis previously reported to FDA that 19 out-of-specification pacers and 10 extended use-before-date pacers had been donated to physicians for use as implants in indigent patients. One of the nineteen out-of-specification pacers was returned unused and subsequently employed for animal work. During a subsequent FDA inspection of October 3-5, two additional donated pacers were discovered--not four as stated in your letter of October 22. These two pacers were given to a local physician, who sent them to Guatemala for implant. We have requested that the physician, Dr. , University Medical School, attempt to obtain information on the names of the patients and the monitoring physicians in Guatemala.

The actual number of donated pacers is, therefore, 31--not 33--and the net number of donated pacers is 30 since one of the pacers was returned for subsequent use in an animal. To the best of our knowledge, this number (30) is accurate. In accordance with your request of October 22, Cordis initiated a comprehensive review of pertinent manufacturing and distribution records dating back to late 1981. The review of manufacturing documents revealed that 74 individual pacers were dispositioned on MRR's to "Scrap-possible Charity candidate." Review of all sales and shipment records, both from the computer and hard copy, show that 31 pacers from these 74 units had been donated. This is documented on either a no-charge sales order or a Cordis "Request for Packaging and Shipment" order. Even though there was no evidence that the remaining 43 pacers had been donated, we reviewed our pacer registry files on implants and found no evidence that the remaining 43 pacers had been implanted. And, finally, we reviewed all letters to physicians who received donated pacers and found no evidence of pacer serial numbers other than those previously reported to FDA. Therefore, Cordis believes that the number of donated pacers (30) is accurate.

With reference to these 30 donated pacers, Cordis has, as previously agreed and stated, informed each doctor that received them of the out-of-specification condition of each pacer and will further request, in those instances where we do not know the names of the monitoring physician and patient, that this information be provided to us.

Cordis further agrees to include, as out-of-specification pacers, the 10 pacers sent to the late Dr. that had their "use before date" extended. These ten pacers and ten others with expired use-before-dates were all sent to Dr. in Poland. While the 20 pacers donated to Dr. by Dr. have expired or extended "use before dates", we do not believe our proposed letter to Dr. is misleading in stating "Cordis is confident that these pacers will provide excellent service." Even though the use-before-date on some of the pacers had expired or was extended as long as 14 months past the initial use-before-date, the service life has not been affected significantly. For example, Pacer 217A-7586, listed in the Table 1, Charity Pacer Implants, was outdated by 14 months at the time (June, 1984) it was given to Dr. for further donation to Dr. . Based upon actual circuit drain measurement of over 2,600 Model 217 circuits in manufacturing, the average circuit drain on the shelf is 3.83 microamps. The circuit drain at maximum current output is 11.4 microamps. This results in a reduction in service life from 15.5 years to 15.1 years even with the 14 month extension. Similarly, Pacer 237-7247 was given to Dr. six months after it was outdated. Based upon actual circuit drain data from manufacturing on over 5,700 Model 237 circuits, the service life is reduced from 15.4 to 15.2 years, even assuming maximum output current during implant. Pacer 333D7-3676, while technically outdated a few days at the time of its donation to Dr. in June, 1984, has a projected service life of 7.5 years, based on actual circuit drain data from over 1,500 333 circuits. This estimate is actually in excess of our original theoretical calculation service life for 333D7 of 6.8 years. With respect to the 10 333D7 pacers that had use-before-dates extended to August, 1985, calculation shows, again based upon actual circuit drain data from over 1,500 333D7 circuits, that the operational service life of such pacers, even when extended to August, 1985, is 7.0 years, slightly in excess of our original predicted service life for this pacer. The original service life predictions on these pacers were developed with very conservative current drain numbers. Actual current drains, based on thousands of production units, are lower. This is the reason "out-dated" pacers still have service lives equal to or in excess of original calculations. Appendix 1, attached to this letter, describes in detail the calculations and data that were used to derive these numbers.

In view of the above, we believe that the statements in our proposed letter to Dr. are not misleading relative to service life. Our redrafted proposed letter to Dr. retains our assurance that the pacers will provide excellent service with the further statement that the maximum service life has been reduced only slightly even though the pacers are beyond their original use-before-date.

The other letters in the attachment have not been changed since FDA has previously agreed with their format and content.

A copy of this letter has been provided to Mr. Casey. We look forward to your review and trust that we can resolve this matter of "Charity" pacers in the manner we are now proposing.

Sincerely,

J N Pagones

John N. Pagones
Vice President
Corporate Product Assurance

Attachment

Miami FL 33102-5700 U.S.A.
Telephone 305-551-2000
Telex 6811112

November 30, 1984

Mr. James Casey
Supervisory Investigator
Food and Drug Administration
6501 N.W. 36 Street, Suite 200
Miami, FL 33166
Dear Mr. Casey:

Cordis is submitting this letter in answer to your request for an interim written response to the FD483 Investigational Observations presented to Cordis at the meeting on November 15. A full detailed response to the FD483 will be prepared and submitted to you on an expedited basis.

Cordis appreciates the constructive tone of the FDA´s review of the FD483 at the November 15 meeting and the emphasis by FDA on timely, voluntary implementation of corrections and improvements. Cordis will make such corrections and improvements in response to the FDA observations as rapidly as possible, giving priority to those areas which were of greatest concern to the Agency. Indeed, some corrections and improvements had already been implemented prior to delivery of the FD483 based on recommendations from the Cordis Regulatory Affairs personnel who escorted the FDA investigators during the inspections. Since November 15, Cordis has completed many additional corrections and improvements. The attached summary describes these initial responses to the FD483 observations. Of course, Cordis will continue to review the 133 observations in detail and will provide FDA with a complete point-by-point response, including all corrections and improvements made or scheduled to be made to meet the Agency´s concerns.

Cordis management is committed to continuous improvement in the quality of Cordis products and services. The FD483 observations will be used as indicators of needed improvements. The FDA´s observations therefore have the full attention of everyone in Cordis management, and the necessary corrections and improvements in response to the observations are being given highest possible priority. Also, the Cordis Board of Directors is actively monitoring Cordis´ response to the FDA´s observations. As you know, Director Patricia K. Woolf, Ph.D. attended the November 15 meeting with FDA to review the FD483.

In addition, on December 3, 1984, the Cordis Board of Directors will consider two basic modifications in the management of the product assurance system. First, the Board will consider the appointment of an independent quality auditor to perform quarterly reviews of the Cordis engineering, manufacturing, product assurance and quality control activities at both the divisional and corporate levels according to an audit plan to be established by the Board of Directors. The independent quality auditor would perform a function analagous to that performed by the independent financial auditors in the finance and accounting functions. Second, the Board will consider the appointment of a standing committee to be designated the "Quality Assurance Committee". The Quality Assurance Committee would be responsible for establishing the scope of the quarterly reviews; for hiring the independent quality auditor; for periodically reviewing quality issues with the internal quality auditors, the independent auditor, and supervisory personnel within Cordis, both with and without Cordis management present. The Board's Quality Assurance Committee would recommend to management, as appropriate, modifications in procedures, changes in emphasis or changes in leadership.

To provide an objective review of current operations for management and the Board and to augment its internal audit group, Cordis engaged the services of two GMP consultants. One is William W. Hines, Ph.D., a Georgia Tech professor, who, as a member of an FDA advisory panel, helped write the device GMP's. The other is Bernard T. Loftus, a retired FDA official who helped write the drug GMP's and was responsible for their interpretation and enforcement while at FDA. These consultants started their own GMP and quality assurance audits of the areas inspected by FDA on November 5, 1984 and are advising Cordis as to appropriate responses to the FD483 observations.

These changes, plus the "Commitment to Excellence Program" described below, are designed to give Cordis the most complete and most strongly emphasized quality assurance program in the medical device industry. They should also insure that FDA's present concerns are promptly remedied and provide an internal system to help prevent similar situations from occurring in the future.

Cordis has initiated the following improvements in systems, records, training and discipline:

1. "Commitment to Excellence" Program

   After months of planning, this program was initiated in the Implantable Products Division in July, 1984 and will begin in the Angiographic Products Division in December, 1984. The purpose of this program is to achieve excellence in all activities, including product design and specifications, purchased material, process capability and control, manufacturing and training with the goal of providing higher quality, more reliable products. The program involves all Cordis division personnel by soliciting information about problems and ideas for corrective actions.

   Also, the program provides an excellent means of communicating to all levels of the organization the vital importance of Cordis products, management's philosophy about quality and the importance of each employee's job in achieving high reliability and high quality. Further, as part of the program, the reliability engineering function has been reorganized and strengthened to improve preproduction design analysis to identify and exploit opportunities for improved reliability. Additionally, a commitment to expanded use of computer-aided-design (CAD) to improve design accuracy is a major part of the Commitment to Excellence program.

   In addition to the beneficial effects of identifying and correcting specific problems, the program already has provided some system improvements in areas covered by FDA observations:

a. Limitations on the use of Material Review Records (MRR) for the release of rejected materials without a validated change in the specification.

b. Reduction in the use of Temporary Authorities (TA) and elimination of extensions of TA's.

c. Requirement that any "use-as-is" MRR release be approved by the Division President or, in his absence, the Executive Vice President or President.

d. Recently eliminated use of "Conditional Releases".

2. Battery Manufacture
The entire battery manufacturing area has been thoroughly cleaned, painted and refurbished to a "like-new" condition. In addition, since most of the observations in the November 15 FD483 concerned battery manufacturing, the initial activities of the Cordis GMP consultants, Dr. Hines and Mr. Loftus, concentrated on this area. To respond rapidly to the FDA's observations and suggestions from the consultants, a Cordis Task Force has been established to review all elements of battery production and to institute necessary changes and improvements in this area. The Task Force has been concerned particularly with specifications, operating and testing procedures, maintenance and housekeeping, training and records. The attached summary of initial responses to the FDA's observations describes a number of changes and improvements already put into effect by the Task Force in the battery manufacturing area. Further improvements will be scheduled and put into effect as rapidly as possible, consistent with appropriate documentation and control.

3. Specifications

The November 15 FD483 includes several observations which relate to acceptance of materials which originally failed to meet their specifications. The materials were reviewed by a Project Engineering Team and accepted on an approved Material Review Record (MRR) or on a Temporary Authority (TA). Many of these rejections and subsequent acceptances are the result of "guardbanding".

"Guardbanding", a common practice in many industries, involves the establishment of specifications for components and work-in-process which are tighter than required by the specifications for the final product. Such "guardbanding" is intended to assure that the final products will always meet their specifications and to direct management attention to "near miss" situations. However, "guardbanding" also results in rejects which are subsequently released because they are within the final product specification. "Guardbanding" is clearly creating regulatory problems for Cordis which far outweigh any possible benefits.

Cordis is reviewing specifications to assure reasonable tolerances and to eliminate "guardbanding". Unnecessarily tight specifications result in the rejection of materials which are later approved for use when the specification is recognized as being unrealistic. The revision of specifications is a monumental job, but whenever a rejection is judged to be unnecessary, a properly documented request to change the specification will be submitted. Thus, specifications will be revised as needed, rather than all at once. In addition, all specifications for new components for implantable products are now reviewed by a senior reliability engineer to ensure that they are realistic.

4. Policies and Procedures

The FDA's concerns about certain Cordis policies and procedures have been evident in the observations contained in several of the fourteen FD483's presented to Cordis in the past year. Cordis agreed that improvements were necessary to assure that these policies and procedures addressed the FDA's concerns. As a result, certain policies and procedures have been revised or are in the process of revision.

Writing and implementing revised Cordis Standard Procedures (CSP's) and Cordis Operating Procedures (COP's) are major, time-consuming tasks. After an initial draft of a policy or procedure revision is prepared, it is reviewed and thoroughly discussed by the directly involved personnel to assure that the revision is practical and enforceable. Also, the effort involved in interfacing with the FDA over the past year has delayed completion of some of the needed revisions because the same personnel who must review and approve the new procedures were directly involved in responding to more immediate FDA questions and concerns.

In the May 31, 1984 letter to Mr. Trujillo, Cordis explained that it recognized the need for changes in certain policies and procedures. Some of these changes have been completed and the others are still being reviewed:

a. CSP 14-01-05. Product Assurance Audits - Completed and sent to Mr. Casey on October 8, 1984.

b. CSP 11-03-01. Control and Reporting of Technical Data - Completed and sent to Mr. Casey on October 8, 1984.

c. CSP 14-08-02. Product Service Reports - A draft was completed to incorporate changes to address FDA concerns, but its publication was delayed to add additional procedures to assure compliance with the Medical Device Reporting regulations. These are included in the attached draft which is in final review.

d. COP 14-03-04. Control of Discrepant Material - The attached working draft was prepared after extensive study by a task force and is now in review.

e. CSP 10-02-03. Product Documentation Change Control - Several changes concerning validation of changes, limitations on Temporary Authorities and document releases are being reviewed by a task force and a draft revision will be prepared soon.

5. Project Engineering Teams (PET's)

Although Cordis management believes that it is aware of the effect on quality of the decisions made by the PET teams and documented by MRR's and TA's, it plans to make changes to address the FDA's concern expressed in Observation 133 of the November 15 FD483. Some of those changes are reflected in the revised Cordis policies and procedures described above. Others relate to the composition and authority of the PET's.

PET's were designed to assure that every product decision is a consensus of the engineering, manufacturing and quality organizations. A specific PET is assigned to each product development project to develop the product and document the development in a device master record. PET's are also assigned to various production areas to initiate, validate and approve changes.

The PET concept has worked well. However, Cordis is reviewing the education, training and experience requirements to assure that PET's are composed of qualified representatives. Also any change in the design, manufacturing processes or testing relating to a product released under an FDA approved 510(k), IDE or PMA submission will require approval by Corporate Regulatory Affairs to assure that required submissions to FDA are made. Further, as indicated below, any decision to use rejected materials "as is" will require concurrence by the Division President, or, in his absence, by either the Executive Vice President or the Chief Executive officer.

6. Sterilization

Cordis employs an "overkill" sterilization method with parameters that are effective in sterilizing highly resistant "biological indicators" that are distributed throughout each sterilization load. These "biological indicators" consist of plastic syringes containing spore strips, innoculated with 10^6 spores per strip and inserted into the space between the sealing rings of the rubber plunger tip of the syringe. The sterilization resistance of these "biological indicators" is evidenced by the fact that their "D" value is 30 minutes in contrast to "D" values of a few minutes for typical biological indicators. Thus, Cordis in confident that all Cordis products have been sterilized effectively.

Nonetheless, Cordis is addressing FDA's concerns about the preconditioning and sterilization equipment. After an initial review of the observations, Cordis discontinued further use of the two-pallet Vacudyne sterilizer until some necessary modifications are made on the unit. To assist Cordis in making the necessary changes rapidly and completing the revalidation studies, Cordis has engaged a gas sterilizer consultant, Mr. Robert Stack. Mr. Stack has more than 20 years of experience in designing, building and validating ethylene oxide sterilization equipment.

7. Failure Investigations and Corrective Action

Several of the FDA's observations related to the need to assure that investigations are made promptly and thoroughly after analysis establishes the cause of a product or component failure and that the results of the investigation and any corrective actions are documented.

Cordis has always performed failure investigations as a basis for considering corrective actions to prevent further failures or to prevent any adverse health consequences from potential failures of distributed products. However, Cordis will improve the documentation of these investigations and the decisions on corrective action. The revised Cordis policies and procedures discussed above contain new requirements to insure the necessary improvements in documentation.

8. 510(k) and PMA Submissions for Changes

In several of the observations in the November 15 FD843, FDA expressed concern about changes which were made by Cordis without prior FDA approval of a 510(k) or PMA supplement submission.

The preamble to the 510(k) regulations indicates that a manufacturer is the "person best qualified" to decide which changes could significantly affect the safety or effectiveness of a device and that a 510(k) is not required for "every change in design, material, chemical composition, energy source or manufacturing process...". Also, in the past, FDA officials speaking at trade meetings, discouraged the submission of 510(k)'s for changes. Cordis has used its best judgment in submitting 510(k)'s in the absence of any more definitive guidelines. Within the past year, however, FDA has changed its policy to require submission of 510(k)'s in situations for which they previously were not considered necessary. Cordis will take the FDA's more stringent current policy into account in future decisions on whether to submit a 510(k) for changes.

Cordis will also review changes more critically relative to decisions on whether to submit PMA supplements. However, it would be helpful if FDA would become more receptive to PMA supplements for changes in effect. Although such supplements, which do not require waiting for FDA approval before implementation of the change, are allowed by the regulations, the FDA Device Evaluation groups actively discourage such supplements except for labeling changes.

As you know, FDA has established task forces to review 510(k), IDE and PMA requirements for FDA approval of changes. Cordis is working with HIMA's industry task forces to develop recommendations in these areas for FDA.

Cordis notes that it has not completed its point-by-point responses to six of the thirteen FD483's received prior to November 15. However, as agreed to by the FDA personnel at the November 15 meeting, Cordis will consider response to the November 15 FD483 as the highest priority. Many of the observations in the six unanswered FD483's were addressed in the September 7, 1984 letter from Mr. Villforth, and subsequent correspondence and Cordis actions have made the responses to those observations less critical. Cordis will, of course, complete the responses to those earlier FD483's after completing the responses to the November 15 FD483.

We hope this response demonstrates Cordis' commitment to make the necessary corrections and improvements in its operations suggested by the November 15 FD483 voluntarily and rapidly. We welcome any suggestions by you and others at the Agency as to how best to accomplish this task.

Sincerely yours,

Norman R. Weldon

Norman R. Weldon
President

Attach.

cc: William F. Hooten
Adam J. Trujillo

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Memorandum
Public Health Service
Food and Drug Administration

Date December 3, 1984

From Acting Director (HFR-4200)
Orlando District

Subject District Conclusion and Enforcement Strategy Mfr: Cordis Corporation
10555 W. Flagler St.
Miami, Fl 33172

To Director, Office of Compliance (HFZ-300)
Center for Devices and Radiological Health

I. PURPOSE AND BACKGROUND

The purpose of this document is to provide updated inspectional findings, propose an enforcement strategy based on recent Orlando District inspections of the Cordis Corporation, and to identify pending issues for the upcoming Ad Hoc Committee meeting scheduled for December 5, 1984.

Orlando District submitted a memorandum dated July 10, 1984, to Director, Office of Compliance, Center for Medical Devices (HFZ-300), which requested the formation of an Ad Hoc Review Committee and provided an overview of our involvement with Cordis as of June 30, 1984, including background, anonymous complaints, inspectional findings, the firm's responses, pending decisions, and enforcement options. We have attached a copy of this memorandum for your reference (attachment 1).

This memorandum will supplement and update the issues identified in the July document.

II. INTERVIEW WITH FORMER EMPLOYEE

Orlando District personnel traveled to , to interview [Cordis Employee] Regulatory Affairs Coordinator, Cordis Corporation, and obtained an extensive affidavit relating alleged safety problems with products; product defects; significant design changes for products without Agency awareness; omission of data and adverse test results from required submissions to the Agency; falsification of information; use of the Temporary Authority (TA) and Material Review Record (MRR) systems for releasing questionable or borderline components; making significant design changes in pacers to enable the use of out-of-specification pacers without notifying the Agency; marketing a lead through packaging configuration without FDA approval; under emphasizing problems conveyed to physicians in Product Updates by "massaging" the statistical data base; implanting new pacer products in humans prior to submission of an IDE; and other statements which reflected on the firm's overall lack of compliance and unwillingness to comply with the Agency's laws and regulations. Copies of this affidavit have been sent to the Ad Hoc Committee members.

Orlando District has been able to document a number of the allegations made by [employee]. An outline of the allegations made in the affidavit and their current status as to whether they have been verified, unverified, not investigated, or require further investigation is submitted as attachment 2. [employee] handled and signed off on the majority of the IDE, PMA, PMA Supplement, and 510(k) submissions from Cordis to the Agency between June 1981 and June 10, 1984 is willing to review any of the documents was involved with while employed at Cordis to point out omissions and how the Agency was misled.

III. INSPECTIONAL FINDINGS

Orlando District's involvement with Cordis began on December 3, 1983. Inspections in December 1983 and January, February, and March 1984, covered the early battery depletion (EBD) Gamma pacer notification, determining the cause of the EBD problem, identifying additional pacers to be included in the Gamma notification, evaluating an internal Cordis audit report of the battery manufacturing area submitted anonymously to the Agency, conducting a GMP inspection of battery manufacturing, documenting the health hazard of sudden failure, and collecting evidence to support a possible 518(b) recommendation.

Our inspections disclosed that Cordis did not submit a 510(k) notification on either the polypropylene or polyimide feedthrough changes incorporated in the design of the lithium batteries (Gamma) which they manufacture.

Our involvement at Cordis during the months of April through August 1984 concerned investigation of two anonymous complaints, received by the Center in March 1984, one of which made numerous allegations. Our investigation was conducted by initiating several different inspections which confirmed the majority of the anonymous allegations including the Lambda and Theta printed wiring board and EBD problems, the software revision/update problems with pacer programmers, the "crosstalk" problem with the Model 415A pacer, and the deficient data on the Orthocor II, Model 284A Antitachycardia pacer which was prompted by the second anonymous complaint. These problems are referenced in the Center's September 7, 1984, letter to Cordis signed by John C. Villforth, Director, Center for Devices and Radiological Health.

These inspections also identified several additional areas of concern including the heat stressed pacers, distribution of out-of-specification charity pacers, lack of 510(k) submission on the Mini-Gamma pacer (Model 340A), the high rejection rate for the torque control balloon tipped catheters due to bonding defects, and the questionable polypropylene protection of the battery feedthroughs for all batteries in the entire product line of Cordis pacers currently being distributed. Each of these safety concerns were also included in the September 7, 1984, letter to Cordis.

Our inspectional visits to Cordis during the months of August and September 1984 were directed primarily to obtaining documentation and updated information on the nine safety concerns identified by the Ad Hoc Committee and listed in the Center's September 7, 1984, letter to Cordis, as well as verifying the September 17, 1984, written response from Cordis.

A. GMP Deficiencies

An inspection, as suggested by the Ad Hoc Committee to determine current compliance with GMP's, was conducted between October 12 and November 15, 1984, and disclosed significant GMP deviations in battery manufacturing. The battery operation was inspected by Victor Spanioli, Orlando District, and Ira Leonard, Physical Scientist, WEAC. Overall our inspectional findings disclosed deficiencies and a continuing lack of control in each of the below listed quality assurance areas. Many of these were identified as deficiencies by the Special Master appointed by the Court as follow-up to the November 1975 Injunction recommendation. At that time, the Special Master (and the Court) advised Cordis that corrections were required in the following areas:

1. Component Specification and Engineering Inadequacies

2. Inadequacies in Formal Documentation of Manufacturing and Inspection Procedures

3. Inadequacies in the Control of Procured Components and Materials

4. Inadequacies in Product Identification and Configuration Management

5. Inadequacies in Traceability, Test Integrity, and the Information System

6. Inadequacies in Material Review Board and Waiver Procedures

7. Inadequacies in Statistical Sampling and Testing Procedures

8. Inadequacies in the Calibration, Operation and Maintenance of Manufacturing Equipment

9. Inadequate Housekeeping and the Failure of Employee(s) to Follow Formal, Internal Cordis Procedures

Inspection of Battery Production

The current inspection of the firm's Power Source (Battery) Manufacturing operation revealed that the firm is not in compliance with CGMP Regulations. The more significant observations include the following:

1. Inspectional personnel responsible for examining Gamma cell lid assemblies, which includes evaluation of the polyimide coating, were not able to routinely accept or reject the assemblies based on the criteria specified in the Operation Sheet.

2. The "Conditional Release" procedure continues to be used to release components pending completion of the required testing.

3. The firm had inadequate controls in place to prevent silane (an adhesion promoter used to enhance polyimide application to glass feedthrough insulators) from being used prior to 12 hours or subsequent to 20 days after its formulation as recommended by the vendor.

4. The firm has not documented the results of their investigation relating to the EBD rate in cell lots 4280 and 4380.

5. The firm did not conduct adequate follow-up when in-process pull tests revealed an unacceptable cell feedthrough pin to current collector welds. An adequate follow-up may have prevented the implantation of a pacer that had failed because of a feedthrough current collector weld defect after being implanted for 7 days.

6. Specification changes are instituted in production without adequate qualification and approval.

   The firm produced approximately 15,000 Gamma and Super Gamma cells that had feedthroughs coated with "diluted polyimide" prior to notifying the Agency of this change and prior to completing qualification testing. These 15,000 cells are in quarantine and the firm intends to destroy them.

7. The firm implemented a specification change which reduced polyimide thickness after it was determined through high temperature testing that thickness, rather than voids within the polyimide, is the critical factor in long term reliability. The revised specification differs from the recommendations of the analyst evaluating the high temperature study failures. Moreover, the individual performing the polyimide thickness measurement was not performing the measurement in accordance with the specification because he had not been included in the distribution of the revised specification. A re-examination by the firm found all previously examined lid assemblies

> reportedly conformed to this specification. The FDA audit, however, determined that lid lot J1884-R did not meet the minimum thickness requirement. These nonconforming lids were assembled in approximately 146 cells under battery lot number 4284B. These cells are currently under quarantine, and Cordis has agreed to notify FDA of the disposition of these cells.

Frank Fischer, President, Implantables Product Division, stated that FDA will be notified prior to destroying these cells. Also, Cordis shipped 1,060 Gamma cells manufactured with the unapproved diluted polyimide application process to their Roden facility in the Netherlands which reportedly are under quarantine and are to be destroyed at the foreign location.

In addition, the firm manufactured approximately 3,000 Theta 1/4 Pi cells using diluted polyimide. However, the qualification tests for this cell resulted in approval of the process change. A 510(k) and/or PMA supplement were not submitted to FDA concerning these changes. The Theta 1/4 Pi cells have been incorporated in pacers and some of these are being distributed.

In order to facilitate a review of GMP deficiencies as they relate specifically to the battery manufacturing area, we have extracted those items from the Inspectional Observations that relate directly to battery (power sources) manufacturing, attachment 3.

Pacemaker Production

Inspection of the pacemaker manufacturing area disclosed that all accepted hybrids did not always meet specification. Therefore, Cordis increased burn-in time for hybrids which initially failed specifications. Cordis currently has hybrids and flex circuits valued at approximately $2 million in quarantine storage which failed specifications or the VT-1 (End of Life) testing. In addition, Cordis has a large number of flex circuits in inventory which they intend to rework by adding a hybrid. The firm's newest hybrid, which reportedly corrected VT-1 problems, was not properly validated. The firm did not conduct all required validation tests, reduced sample size, and modified some validation tests. Additionally, the firm failed to notify the Agency of these changes.

Other inadequate validation includes the qualification of Celgrad (polypropylene) used as the battery cell separator material, extending the "use before" dates for approximately 650 Model 333D7 pacemakers manufactured in the fall of 1982 through the use of three separate TA's, ETO sterilization of pacemakers, and heat distribution temperatures in ovens.

One lot of reed switches initially failed receiving inspection but part of the lot was released by the Material Review Board. Of the 846 reed switches released, 12 failed in pacemakers which were distributed, including four pacemakers which had to be explanted. Also one pacemaker failed in-vitro life test which had this same reed switch lot number.

The firm's investigations of returned pacers are inadequate. If a component fails, the firm does not investigate to determine if there is any correlation between component lot numbers as exampled above, or known pocket infections to sterilization loads. Also, the firm fails to document what corrective action, if any, was taken to prevent recurrence of the failure.

B. Polypropylene Protected Feedthrough

The polypropylene design change included in the pending 510(k) notification may not adequately prevent corrosion of the glass feedthrough which may lead to EBD due to self-discharge. This is a time-related problem which may affect and significantly shorten the service life and normal end-of-life indicator of the batteries.

The most recent cumulative survival for EBD as of November 5, 1984, in all Gamma pacers containing polypropylene-protected cells is 99.4% versus 74.6% for Gamma pacers containing unprotected cells which were subject to the Gamma notification, for the same time period of 47 months. Currently, there are 34,889 implanted pacers with polypropylene protection. There have been 41 EBD's from this group (.12%). In comparison the cumulative survival with respect to EBD for pacers with batteries from cell lots 4280 and 4380 at 46 months, is 96.0% and 97.0% respectively. Seventeen (17) of 623 implants from cell lot 4280 and six of 551 implants from lot 4380 have experienced EBD (a failure percentage of 2.73% and 1.09%, respectively).

The in vitro life test data seems to parallel the field performance of cell lots 4280 and 4380 in that there has been three out of five (60%) EBD's in lot 4280 and two out of four (50%) EBD's in lot 4380 involving reserve cells stored under 115K ohm load at 37° C. Additional random depletions have occurred in Gamma reserve cells from lots 4480, 5080, 1481, and 2581.

Significantly, the firm has reported on the recent failure of one out of ten (10) cells undergoing special high temperature testing from lot 3481 (having polypropylene-protection) that was stored at a temperature of 60° C for 299 days. The projected time to failure at 37° C for this cell is calculated at 48.6 months.

Cordis submitted a listing of extensive testing for voids in the polyimide feedthrough coating after the current GMP inspection was concluded. The Agency was not previously aware of all these tests. This listing was provided to CDRH (HFZ-450).

C. Crosstalk Problem

Cordis issued a Product Safety Alert on Potential Crosstalk in Early Gemini 415A Pacers with Dual Anodal Rings on October 23, 1984. The crosstalk problem was described in our July 10, 1984 memorandum.

D. 510(k) Notifications

Cordis submitted a combined retrospective 510(k) notification on April 4, 1984, for both the polypropylene and polyimide battery feedthrough changes, as verbally requested by the Center on December 7, 1983. An Equivalence Summary concerning 510(k), K841414, dated June 5, 1984, was submitted by Cordis. This 510(k) is still under review by the Center. Cordis has physically withdrawn from sale 48 pacers from their salesmen of various models which incorporated polypropylene protected feedthroughs in their battery cells. However, Cordis did not recall pacers on consignment and not yet implanted. Further distribution of 108 additional pacers in inventory which incorporated the polypropylene feedthrough has been discontinued pending a response by FDA to the 510(k) submission.

Cordis has not submitted a 510(k) on the Mini-Gamma Model 340A pacer. The firm has physically withdrawn from sale 31 Model 340A pacers from their sales force. However, they did not recall pacers on consignment and not yet implanted. Further distribution, except for those pacers on consignment, has been discontinued pending submission of the 510(k).

Cordis has failed to submit a notification to the Agency of the changes initiated to correct the printed wiring board used in the Lambda pacemakers Nos. 208, 217, 221, 232, 235, and Theta 237. Also, Cordis did not notify the Agency of the immediate burn-in change to correct the EBD problem in Lambda and Theta pacers.

On November 14, 1984, the District provided to Cordis Corporation a listing (see attachment 4) of approximately 20 products being marketed which may require either a 510(k), IDE, PMA, or PMA Supplement submission to the Agency. The Center has previously been notified of these products and Cordis has submitted a response dated November 21, 1984.

E. Other Products Causing Adverse Reactions

Cordis has not notified the Agency in a timely manner of potential health hazards associated with defective or failed devices or of significant design changes. On more than one occasion the firm has made design changes or modifications to their products to correct a problem but continued to distribute their inventory of the affected product without the corrected modification, i.e., unprotected battery feedthrough, printed wiring boards, et al.

1. Printed Wiring Board and Early Battery Depletion

In the Center's letters dated September 7 and October 22, 1984, Cordis has been requested to send Notification Letters to physicians concerning failures due to failed printed wiring boards and EBD. The firm maintains that Product Updates are sufficient notice to the medical community. Communication between the Center and Cordis on this point is continuing, but the firm has verbally stated that they do not intend to notify. The most recent Product Update, Number 17, October 1984, mailed on November 9, 1984, does not list all pacer models which the District has identified as being affected by the printed wiring board problem which can lead to abrupt failure. Also, the Product Update does not mention the EBD problem associated with the Lambda and Theta pacers. The most recent Product Update for the Lambda and Theta pacers is flagged "IMPORTANT! PACER MONITORING INFORMATION". However, the District does not believe that this constitutes adequate notification to assure that the monitoring physician was notified to assure that proper monitoring will take place where sudden failure of a defective product may be involved.

Orlando District believes that a definite hazard exists with the Lamda and Theta pacers with the printed wiring board and EBD problems and proper notification should be made under section 518(a) of the Act.

2. Polyurethane Leads

Orlando District has completed the recent field assignment on polyurethane and collected samples (84-374-543/4) of the extruded polyurethane tubing. We have not received a written response to our recall recommendation endorsement and May 9, 1984, memorandum regarding 235 cardiac leads (Models 332-745 and 322-760) and 195 spinal leads (Model 691-102) manufactured with the Texin MD 85A polyurethane. Also, when the clinical study of cardiac leads manufactured with Texin MD 85A polyurethane containing 30% barium sulfate was terminated, the firm could only account for 64 of the 177 leads distributed/manufactured. One hundred thirteen (113) leads remain unaccounted for.

3. Heat-Stressed Pacers - Gamma and Theta Models

Two hundred thirty-one (231) pacemakers were subjected to gas analysis testing involving a temperature of 115° C or above for undetermined periods of time. In spite of this, the pacers were distributed and approximately 150 were implanted. In some pacers the battery cells were replaced with cells which had not been subjected to the elevated temperatures. The firm has initiated a notification to physicians and hospitals to advise them of the potential problems with these pacers and to recall any pacers which have not been implanted [recalls Z-059-5 (Theta Models) and Z-060-5 (Gamma Models)]. However, the firm notified Cordis Europa, Roden, Holland, on only 19 of 183 heat stressed pacers distributed in Europe.

4. Charity Pacers

In FDA letters to Cordis of September 7 and October 22, 1984, the firm was advised that FDA was aware that at least 33 pacers which did not meet all specifications were donated to charity. The firm responded that 10 pacers should not be included because the "use before" date had been extended. The firm was requested to notify physicians of the out-of-specification condition of each pacer shipped to or being monitored by them. We also requested the firm make a file search to identify additional out-of-specification pacers which may have been distributed.

By letter dated November 20, 1984, to CDRH, Office of Compliance, the firm stated that only 21 out-of-specification and 10 extended use before date pacers had been donated as "charity pacers." Of these, one had been returned to the firm and had been used "in an animal." Therefore, 30 donated pacers appears to be accurate. The firm further stated that each physician who received them has been informed of the out-of-specification condition of each pacer.

The firm's previously identified letter states that a review of records revealed an additional 43 pacers that had been dispositioned as "scrap-possible charity candidate." Cordis is unable to determine from their records the final disposition of these 43 pacers. Further investigation by Orlando District investigators is necessary to determine if these pacers were distributed, reworked, or actually scrapped.

5. Pacemaker Programmers - Software Revisions

All pacer specific instructions supplied with the Model 233F and Model 415A contained an addendum which informs the physician of the procedure for turning off the "back-up" mode. A number of physicians and hospitals having Cordis programmers were not furnished adequate software revisions to allow them to properly program the 233F and 415A models to get the pacer out of backup mode by pushing the "Stat-Set" button as stated in the labeling for the pacers.

The firm is sending addendums to instructions to all programmer users but does not plan to issue a notification on this problem. The firm has submitted PMA supplements as requested by CDRH.

6. Orthocor II Antitachycardia Pacemaker Model 284A IDE

Export approval has been withdrawn and complete animal test data has been requested. Orlando District feels that the IDE inspection was comprehensive in nature and that there are additional significant deficiencies in addition to the incomplete animal test data.

7. Complaint Files - Missing Information

At least 57 Cordis complaints have been identified which were located in Cordis' legal department but were not included in the regular consumer complaint file accessible to FDA. Cordis has refused to allow FDA investigators to review their legal files. Cordis has provided photocopies of selective documents which they identified as source documents which most often do not contain complete information. We were unable to determine if: (a) all complaints were provided by Cordis and (b) whether significant information on each specific complaint has been withheld. We have identified inconsistencies in complaint tabulations which Cordis has provided.

8. Inadequate Failure Investigation

Cordis has failed to investigate numerous product failures. Also, Cordis has stated that it is not company policy to investigate patient deaths to determine if their device was involved unless the device is returned to Cordis or the physician or another individual registers a complaint.

F. Possible Obstruction - Failure to Notify FDA

Several incidents have occurred that raise questions regarding management's intent to comply with the statute and regulations enforced by FDA:

1. A memo from John N. Pagones, Vice-President, Corporate Product Assurance, addressing a task force assignment to investigate the battery depletion problem in Gamma cells and Gamma pacers was revised prior to being given to FDA to eliminate eight comments pertaining to specific areas to be investigated.

2. Failure to log, document investigations, and evaluate complaints and potential or actual lawsuits as adverse reactions.

3. Failure to submit 510(k) notifications for significant changes in device design such as the polypropylene or polyimide protection added to the glass feedthrough of the Gamma cell. Cordis implemented another change in feedthrough protection (diluted polyimide) without notifying the Agency and started full scale production prior to this change being fully qualified.

4. Failure to provide complete information with 510(k) submissions on the Gamma pacers and polyurethane leads.

5. Failure to advise FDA within 10 days of adverse reactions relating to crosstalk in the Gemini pacers as well as other adverse reactions.

6. Failure to provide complete and accurate data in their IDE submission for the Orthocor II pacer.

G. Cordis Responses

Cordis management has stated that decisions made on the design and marketing of the products initially, as well as the changes instituted afterward, were made with the current state-of-the-art technology. They maintain that hindsight should not be used in evaluation because the problems were not evident, but developed over a period of time. They contend that the unprotected glass feedthrough problem constituted state-of-the-art technology that could not be prevented. Cordis management believes that the polypropylene and polyimide corrections have solved the feedthrough degradation problem. In general they maintain that the firm strives to comply with Agency regulations and GMP's.

Cordis has submitted four written responses during our investigation. On June 1, 1984, Cordis representatives prepared a written response dated May 31, 1984, to District personnel in Orlando. The response consisted of two volumes of documents, speaking to GMP's and other violations and their correction or disagreement with FDA-483 observations relating to the Gamma pacers. The second response dated June 2, 1984, was presented to Miami Resident Post personnel. This document contends that pacers containing cells with polypropylene protected glass feedthroughs are safe and effective. The third response to Inspectional Observations of April 6, 1984, May 15, 1984, and April 27, 1984, was received by the District on July 2, 1984, and is undergoing review. The fourth response to the IDE inspection was dated August 10, 1984, and is also undergoing review. Copies of all responses have been provided to CDRH.

Cordis has not responded adequately to each of the safety concerns contained in the September 7, 1984, and October 22, 1984, letters from CDRH.

H. Pending Evaluations

Copies of the inspection reports and exhibits have been forwarded to the Center for Devices and Radiological Health (CDRH) as completed. In addition, ORL-DO has submitted the following documents to update or recommend action by the Center.

1. On May 9, 1984, we submitted a memorandum to CDRH, Division of Compliance Operations (HFZ-323), requesting review and evalution of an inspection concerning polyurethane pacemaker leads. The inspection conducted March 15 - April 6, 1984, disclosed that the firm continued distribution of polyurethane (Texin MD85A) leads that had been released but were made of materials that did not resist surface cracking. We have not been advised of CDRH's evaluation.

2. On June 27, 1984, we submitted a memorandum to CDRH, Office of Compliance (HFZ-300), requesting evaluation of our concerns that Gamma pacers containing batteries with polypropylene protected glass feedthroughs may fail due to EBD. We also requested consideration be given to disapproving the pending 510(k) notification and advising the firm to cease marketing Gamma pacers containing batteries with polypropylene protected feedthroughs pending submission of further studies to demonstrate effectiveness. We have not been advised of CDRH's evaluation.

3. On October 16, 1984, a memorandum from the Miami Resident Post dated October 12, 1984, regarding comments concerning the September 17, 1984, letter from Cordis to Mr. Villforth was endorsed to CDRH, Division of Compliance Operations (HFZ-320). This memo requested a written reply regarding the exportation of Model 261 pacer, that did not contain the rate limiting (runaway) circuitry, as to whether this constituted the shipment of a component or a finished device. This pacer undergoes full final electrical testing at Cordis, as a normal pacer would. The firm claims the product shipped to Uraguay is not a finished medical device. We have not been advised of CDRH's evaluation.

4. Orlando District has requested guidance on approximately 600 pacers, Model 333D7, manufactured in October, November and December 1982, whose "use before" date was extended until August 1983 through the use of three separate TA's. We have not been advised of CDRH's evaluation.

I. Responsibility

Although our documentation to date does not identify any one individual to have acted with intent to manufacture and distribute adulterated and misbranded devices, the problems encountered, combined with the decisions made to continue marketing Class III uncorrected devices that later developed serious problems, are indicative of severe deficiencies in management's ethics and control of operations. We believe the firm's reliance on "state-of-the-art" as a defense for not properly addressing these problems, is unacceptable.

Our most recent GMP inspection disclosed that substantial changes have been made to reduce the use of Material Review Records (MRR's) and TA's and the firm is currently preparing a document to explain the changes which have been made or they intend to make in the area of implantable devices.

J. Monitoring of Components

The recent GMP inspection also disclosed that Cordis has several lots of components which were rejected, did not meet specifications, did not pass qualification testing, or were authorized for shipment by Cordis even though they did not meet the vendor's final specification. Orlando District will monitor the final disposition of the following components:

1. Approximately 15,000 Gamma cells valued at approximately $500,000 which were manufactured with the unapproved diluted polyimide application process and did not qualify for release.

2. Approximately 1,677 hybrids which did not meet the vendor's final specifications or Cordis test specifications, and approximately 644 flex circuits that did not meet specifications (Cordis may attempt to add a small hybrid to, to bring them within specifications). These are valued at approximately $2 million.

3. Approximately 146 battery cells, lot 4284B, which were rejected after a third examination of a cross-section of the lid lot revealed that the polyimide coating did not meet minimum thickness specification.

IV. DISTRICT RECOMMENDATIONS FOR REGULATORY AND ADMINISTRATIVE ACTIONS

Orlando District recommends that the Ad Hoc Committee consider one or more of the following options:

1. Referral to the U.S. Attorney for a Grand Jury Investigation to establish individual responsibility, obtain records, etc. Prior to Grand Jury investigation, [employee] should be afforded the opportunity to review the IDE's, PMA's, and PMA supplements which had a part in submitting while employed by Cordis Corporation for the purpose of identifying falsified and deliberately misleading information.

2. Consideration of citation under section 305.

3. Consideration of section 518(b) of the Act to order refund or replacement costs to patient recipients of one or more of the following:

a. All Gamma pacers that contain batteries with unprotected feedthroughs.

The 6200 Gamma pacers containing batteries with unprotected feedthroughs that were distributed after November 1980, when polypropylene protection was added to cells used in Gamma pacers.

b. The 30 out-of-specification pacers donated as "charity" pacers.

c. The approximately 25,000 Lambda, Theta, and Stanicor Q and R pacers which may fail due to unfilled plated through holes on the printed wiring boards.

d. The heat-stressed pacers distributed.

4. Notify firm in writing of problems and a meeting with the Center or District to discuss voluntary correction/consent agreement concerning compliance with current GMP's and resolution of any pending problems listed in this memorandum or the Center's letters to the firm.

5. Consideration under section 515 of the Act to withdraw approval of the PMA for the Gemini and Sequicor pacers under (e)(1)(A), (e)(1)(B), and/or (e)(1)(C).

6. Consider nonapproval of the pending 510(k) notification concerning the use of polypropylene and polyimide protection to the battery glass feedthrough until additional studies have been completed to demonstrate its safety and effectiveness. This application has been pending in CDRH since April 1984.

7. Advise the firm regarding the inadequacy of the polypropylene protection and consider asking the firm to notify physicians on cell lots 4280 and 4380. Reportedly, all pacers incorporating cell lot 4180, whether protected or unprotected, were included in the Gamma notification.

8. Require that Cordis expand their physician notification to include the 164 heat-stressed pacers in which the batteries were reportedly replaced by the Roden facility prior to distribution or implantation.

9. Request that the firm submit a 510(k) notification promptly and that all pacers incorporating cells with the diluted polyimide that are not yet implanted, including all those on consignment, be recalled and all inventory on hand be withheld from distribution.

10. Request Cordis to notify physicians of the pacer programmer software problem and that they initiate steps to assure that all programmers in the field be furnished updated software.

We believe these options should be discussed during the Ad Hoc Committee meeting on December 5, 1984, with a view toward determining a final regulatory strategy for Cordis Corporation.

E. L. Brisson
Ernest L. Brisson
Acting Director
Orlando District

Attachments

cc:
HFC-20/Shumate
GCF-1/Levine
HFR-41/Kinslow

First Draft: Casey/Spanioli/Rinc/Tunks/Miceli/mal 11/21/84

Second Draft: EB/ERA/CCR/JJM/dar/11-28-84

Third Draft:dar/11-30-84

3rd Draft Distribution:
HFZ-300
HFR-41/Kinslow
HFR-4200/EB (2)
HFR-4240/ERA/JJM
HFR-4250/CCR
HFR-4575/JAC

Final:dar:12-3-84

Final Dec'd (12/4/84) to:
HFZ-300/Gundaker
HFC-20/Shumate
GCF-1/Levine
HFR-41/Kinslow

bcc (Final):
HFR-4200/AJT/ELB/EI File
HFR-4240/ERA/JJM/CB File
HFR-4250/CCR
HFR-4575/JAC

[Please see above item in chronology for Attachment 1, July 10, 1984 Memorandum]

ATTACHMENT 2

ALLEGATIONS OF [Cordis Employee]
September 21, 1984 Affidavit

Memorandum dated September 28, 1984, endorsed to Orlando Compliance Branch October 19, 1984, discusses the statements made by [employee] in affidavit signed on September 21, 1984. The following outline coincides with the items discussed in the affidavit.

1a. (Pages 3-6): Based on the investigation completed thus far, it appears that Cordis has properly rejected circuits that did not meet VT1 and VT2 requirements. However, our limited resources have not allowed us to investigate this area thoroughly. Additional work remains to be done regarding adequacy of qualification which led to the selective usage of circuits that appeared to be stable and the rejection of those circuits that were not stable. Not verified.

1b. (Page 12, #9): 415A case regarding depleted battery - This may have been confirmed but the depletion was due to a circuit malfunction unrelated to early EOL indicators. We have not seen any failures at Cordis regarding early activation of EOL indicators contrary [employee] position. Tanenzaft states that he is unaware of such failures. We may need to question Schwoebel, Pagones, Leetmaa, Weinberg and others to definitely confirm or refute this allegation.

2. (Pages 6-9): Allegations regarding Orthocor II - Orlando District has conducted an IDE inspection of the Orthocor II Model 284, and our findings generally supported the allegations within the affidavit.[employee]stated that would review Orthocor II submission or any other Cordis submission so that can identify information that was not accurate or complete.

3. (Pages 9-10): Deficiencies in the Material Review Record System have been confirmed. A specific example cited by [employee] relating to the use of substandard hybrids used in Sequicor D/E pacers has not been investigated. Investigation may not be warranted as the majority, if not all of these 2-year pacers, have reached the end of their service life.

4. (Page 10): Changes authorized by TA's and not notifying FDA of these changes. This has been confirmed during the recent GMP inspection and previously.

5. (Pages 10-11): Allegation of falsification, manipulation, and omission of data regarding IDE/PMA/510(k) submissions to FDA. Any prosecution recommendation should consider affording [employee]an opportunity to review submissions has personal knowledge about.

6. (Page 11): Allegation that the firm deliberately hid complaints from FDA has not been verified. Approximately 58 complaints located in the legal department, not accessible to FDA, were identified during our inspection.

   Allegations that firm seldom considered a complaint to be a hazard is accurate. Firm's policy has changed and a more stringent definition of the term "hazard" is in use.

7. (Pages 11-12): The "crosstalk" complaint not reported to FDA has been verified. Mr. Hershenson stated that he was not involved in the decision not to notify FDA of the complaint, contrary to [employee] allegation.

8. (Page 12): Overdrive pacing at greater than rates of 300 using the 415A has not been investigated due to our limited resources and other priorities.

9. (Page 12): Discussed as item 1b above. With respect to Cordis not reporting failures in IDE/PMA submissions occurring outside the United States, this was confirmed during the crosstalk investigation.

10. (Pages 12-13): The allegation regarding the 402 pacer 510(k) not being accurate has not been evaluated. The allegation that out-of-specification circuits were used in 402 pacers because they were 510(k) devices has not been investigated.

11. (Page 13): The allegation of the development and marketing of the Multicor S and other "salvaged" pacers has not been completely investigated. Cordis has listed an "S" type pacer in their literature index available to salesmen. However, Cordis has stated that this represents a new Gamma pacer which is the subject of a 510(k). This has not been confirmed or refuted.

12. (Page 13): Allegation of the distribution of a variety of programmer software for Gemini based pacers has been confirmed. This is an issue discussed by the Ad Hoc Committee. The Center should review this item and discuss whether or not further follow-up is necessary. For example, all programmers do not contain the most recent EPROM which would include the most recent software revision.

13. (Pages 13-14): The allegation that programmers were marketed that contained the wrong foreign language EPROM's has not been investigated.

14. (Page 14): The allegation that Cordis did not submit a complete PMA for the 233F has not been evaluated. This should be addressed by CDRH, Division of Cardiovascular Devices.

15. (Page 14): Item 15 was confirmed.

16. (Pages 14-15): Item 16 and 17 had been previously investigated.

17. The reasons for the testing criteria stated to FDA differ from the reasons stated by [employee] Additional investigation is required to confirm or refute this allegation.

18. (Page 15): Item 18 was confirmed.

19. (Page 19): The shipment of out-of-specification circuits was confirmed. However, the use of circuits that did not meet specifications was not confirmed.

20. (Page 15): This was confirmed.

21. (Pages 15-16): This was confirmed.

22. (Page 16): Not investigated.

23. (Page 16): Not investigated.

24. (Pages 16-17): Not investigated.

25. (Page 17): Confirmed by Stephen J. Tunks.

26. (Page 17): Not confirmed based on verbal statements. Not fully investigated through a records review.

26a. (Page 17): Confirmed - 200 cell study.

27. (Page 17): Consultant visited Cordis in early 1984. Confirmed.

28. (Page 18): Not investigated.

29. (Page 19): Not investigated.

30. (Page 19): Concur with observation as often times, due to time constraints, background data would not be requested. However, we have not been able to confirm that certain documents were specifically removed by Mr. Schwoebel or Mr. Pagones prior to requested information being provided to FDA. However, we suspect that this may have occurred. Probably would require a Grand Jury to find this out for certain.

31. (Pages 19-20): Not investigated.

32. (Pages 20-21): This area has been fully investigated and [employee] allegations are basically correct with the exception of the comments relating to the reasoning behind selecting the feedthrough as being the cause of EBD's. The feedthrough failure mechanism was identified as being responsible for EBD's not because it was self-serving, but because that appears to be the actual failure mechanism.

33. (Page 21): Have not seen any EOL problems with current Super Gamma cells being manufactured. Due to resource and time constraints we have not fully investigated if the initial Super Gamma cells manufactured had EOL problems or whether they were used in manufacturing pacers.

34. (Page 21): Reference to changes in the Theta 1/4 Pi battery relate to reduction in electrolyte. This has been previously investigated and confirmed. With respect to Super Gamma cells, that did not have an EOL period, being used in 233GL and 418 pacers, this has not been investigated. Reportedly, based on verbal accounts, those cells were not used in production.

35a. Problems with the interactive programmers have not been investigated.

35b. Confirmed by Investigator Stephen J. Tunks.

36. (Page 22): Investigated by Stephen J. Tunks and confirmed. The Crawford Cell System used to conduct EMI testing had not been validated. Also, this EMI testing had questionable pass/fail criteria.

37.
and
38. (Pages 22-24): The polyurethane leads with Texin MD85A polyurethane manufactured by Mobay Chemical were investigated and a complete report was provided. The clinical trials were completed prior to IDE regulations being in effect. Therefore, Cordis never notified FDA of problems. Objections during the two inspections were that the implanted Texin MD85A polyurethane degraded in rabbit muscle testing. Complaints received during the clinical trials were never entered into the complaint file and excess leads distributed during the clinical trial were never recovered. Also, the firm continued to sell some leads after they knew the results of the degradation testing. The firm has never notified physicians of these potential problems. Texin MD85A polyurethane was used in Atrial J leads, Elcor ventricular carbon leads and spinal leads.

Cordis has never referenced any carcinogenicity or toxicity of the leads. This carcinogenicity was not investigated. Mobay Chemical should be contacted and Cordis investigated regarding carcinogenicity of the polyurethane. According to Cordis, carbon filled leads were discontinued because they were too difficult to manufacture and multifilar leads corrected the lead breakage problem. The Atrial J and spinal leads were stopped due to degradation in rabbit testing. The polyurethane issue is pending at the Center. This issue was not addressed in Mr. Villforth's September 7, 1984, letter to Cordis.

DEC - 6 1984

Richard S. Morey
Kleinfeld, Kaplan and Becker
1140 Nineteenth Street, N.W.
Washington, D.C. 20036

Dear Mr. Morey:

This is in response to your letter to Mr. William H. Damaska dated October 31, 1984 regarding the need for Cordis to notify physicians of defects in Lambda and Theta pacers.

The information provided in the product updates is, as you describe in your letter, in the form of "general knowledge" about the Lambda and Theta pacers. The overall thrust of the updates seems to emphasize the positive aspects of the performance of the pacers as is indicated by the title "Achieved Reliability of the Lambda (or Theta) Series Pacers." While we recognize that specific issues of the Lambda Series updates, e.g., the April 1982, October 1982, and April 1983 issues do reference the sudden no output nature of the printed wiring board failures we also observed that there was no discussion of this in the April 1984 issue. The Theta Series updates do reference the sudden no output problem in the April and the November 1983 issues but there is no reference to the problem in the subsequent April 1984 issue. In all cases the information is not highlighted or emphasized and, therefore, does not adequately alert the physicians to the potential problem.

We cannot agree with you that FDA has been aware of the Lambda and Theta defects for three years. Our records show that your December 9, 1982 letter to Mr. Donald Dahms indicates that malfunctions of the electron circuit "might occur suddenly without warning." However, the data available currently indicates that this, in fact, has occurred. Letters to individual FDA reviewers with copies of product updates which have already been sent to physicians is not an acceptable alternative to either (a) official notification to FDA of a device failure or (b) a premarket notification to FDA when the failure mode leads to a change in the device that is intended to correct, for example, a design problem.

Regarding your comment that these defects would not be reportable under the new medical device reporting regulations, again the key to the answer is sudden no output failure. Since the labeling does not address sudden no output we would expect a firm to report this failure to FDA.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

We have also asked the members of our Circulatory System Devices Panel for an opinion regarding the overall adequacy of periodic notices issued by manufacturers to physicians or other health professionals. The concensus of the Panel was that identifying device failures along with other information in product updates is not an acceptable alternative to providing specific recall letters to physicians.

In summary, we think that due to the potential health risk associated with sudden no output defects, all physicians should be notified. We again request a draft of the proposed notification letter for review.

Sincerely yours,

Walter E. Gundaker, Director
Office of Compliance
Center for Devices and
Radiological Health

Prep:TMM:11/14/84; Revised:WHD:11/16/84; TMM:11/19/84; WHD:11/23/84;
ABH:11/26/84 WEG:11/27/84; TMM:12/3/84 R/D:GAR:11/16/84;
Revised:GR:11/23/84; GAA:11/23/84; RR:12/3/84; F/C:RR:12/4/84

12/6/84

cc: Norman R. Weldon, Ph.D., President
Cordis Corporation
10555 West Flagler Street
Miami, Florida 33172
HFZ-320
HFZ-300 HFZ-321 HFZ-323 HFZ-440 HFC-20 (M. Schumate) HFR-41
HFR-4200 HFR-4575

FILE
OPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
320	Damask	12/6/84						

P.O. Box [illegible]
Miami, FL 33102-5700 U.S.A.
Telephone 305-551-2000
Telex 661112

December 14, 1984

Mr. Walter Gundaker, Director
Office of Compliance (HFZ-300)
Center for Devices and Radiological Health
8757 Georgia Avenue
Silver Spring, MD 20910

Reference: (1) Letter of October 22, 1984 to Dr. N. Weldon from W. Gundaker (Holt)

(2) Letter of November 20, 1984 from J. Pagones to W. Gundaker

Dear Mr. Gundaker:

I have enclosed copies of the various letters that we have mailed today to physicians in connection with the "Charity" pacer notification. After recent discussions with Mr. Casey, we have labeled the letters and envelope IMPORTANT PACER NOTIFICATION. The content of the letter to Dr.   has been changed to reflect the requirements expressed in your letter of October 22 to Dr. Weldon.

We have recommended to Mr. Casey that this notification be considered Class III and trust that this will be the ultimate decision.

Sincerely,

J N Pagones

John N. Pagones
Vice President
Corporate Product Assurance

JNP:mda
Enclosure

cc: Mr. J. Casey

JAN 10 1985

Richard S. Morey
Kleinfeld, Kaplan, and Becker
1140 Nineteenth Street, N.W.
Washington, D.C. 20036

Dear Mr. Morey:

This is in reply to your letter of December 11, 1984 to Mr. William H. Damaska regarding the Cordis Programmer III and the proposed letter to accompany the new programming instructions.

We believe that inadequate programming instructions may result in unnecessary pacer explantation and replacement exposing the patient to a moderate risk that is associated with any surgical intervention. With this in mind, we think it is important that the Cordis cover letter state the problem in the first paragraph. The current draft does not do this, in fact, the possibility of risk is not mentioned. We have indicated suggested changes on the enclosed draft.

The FDA plans to classify this action as a Safety Alert and the letter should be labeled as such, (e.g. "CORDIS PROGRAMMER III SAFETY ALERT").

We do not believe that the problem with the Cordis programmer is similar to the issue which you referred to in your December 11 letter. The labeling in the Cordis situation is inadequate because it does not provide adequate directions for use. The labeling was adequate. The problem resulted from user misinterpretation. The situation was compounded because the dialysate was produced and labeled by another firm also under that firm's label. Therefore, had no apparent direct responsibility.

We note that even though the letter was considered by FDA to be a voluntary corrective action, the firm did begin their letter, "Warning - ..... injury". We think this is an appropriate way to begin a letter which is intended to notify health professionals of potential hazards.

Sincerely yours,

Walter E. Gundaker

Walter E. Gundaker, Director
Office of Compliance
Center for Devices
and Radiological Health

Enclosure

cc: Norman R. Weldon, Ph.D., President
Cordis Corporation
10555 West Flagler Street
Miami, Florida 33172

[illegible]

VINCENT A. KLEINFELD
ALAN H. KAPLAN
ROBERT H. BECKER
THOMAS O. HENTELEFF
RICHARD S. MOREY
PETER O. SAFIR
MARC H. SHAPIRO
NANCY SINGER
KINSEY S. REAGAN
PETER R. MATHERS
DAVID E. KAPLAN

LAW OFFICES
KLEINFELD, KAPLAN AND BECKER
1140 NINETEENTH STREET, N. W.
WASHINGTON, D. C. 20036

TELEPHONE
(202) 223-5120
TELECOPIER
(202) 223-5619

WHD
1/16/85

January 16, 1985

Mr. William H. Damaska (HFK-110)
Food and Drug Administration
8757 Georgia Avenue
Room 1248
Silver Spring, MD 20910

Dear Mr. Damaska:

This will acknowledge Mr. Gundaker's letter of January 10, 1985 replying to my December 11, 1984 letter to you concerning the Cordis Programmer III and the proposed letter to accompany the new programming instructions.

We enclose a further revised draft of the proposed letter for your consideration. Cordis disagrees with the suggested addition to the earlier draft enclosed with Mr. Gundaker's letter as being factually incorrect. However, it has modified the letter to accomplish the same purpose of alerting physicians to possible problems based on not understanding the limitations of the programmer software. We request prompt consideration of this new draft so that the instruction may be sent out as soon as possible.

Cordis appreciates the agency's decision to classify this action as a safety alert rather than as a notification or recall. However, Cordis still does not understand the basis for distinction between this situation and the situation which apparently has not been classified even as a safety alert by FDA.

Cordis disagrees with Mr. Gundaker's letter that its prior labeling was inadequate in not providing adequate directions for use. That labeling clearly required the user to set the correct pacer model setting on the Programmer III before using it to program a particular model pacer. In the one incident known to Cordis, the physician failed to follow these directions and attempted to reprogram a pacer with the programmer set to program a different model pacer. When the programmer did not reprogram the pacer under these circumstances (as it should not), the physician performed an unnecessary explant operation.

In Cordis' view, this situation is not significantly different from the situation. In each case, there were adequate directions for use which were violated due to user misinterpretation. In each case, an injury to a patient resulted -- in the situation death and in the Cordis situation only an unnecessary explantation. While Cordis could understand both of these situations being classified as "safety alerts," it is unable to see any reason why the Cordis situation should be so classified if the incident was not.

Cordis wishes to expedite conclusion of this matter and transmit this information to the users of Programmer III. Accordingly, it is willing to send out the enclosed draft letter as a "safety alert," if the text is otherwise acceptable to FDA.

Please let us know as soon as possible how to proceed.

Yours very truly,

Richard S. Morey
Counsel for Cordis Corporation

RSM/jlr

Enclosure

IMPORTANT!

SAFETY ALERT

NEW INSTRUCTIONS FOR PROGRAMMING CORDIS PACERS WITH

PROGRAMMER III, MODEL 255A

Dear Doctor:

Cordis has received a report of an unnecessary pacer replacement after an unsuccessful attempt to reprogram the unit with a Programmer III, Model 255A, set to the wrong pacer model. This error was possibly caused by the physician not understanding the limitations of the programmer software which could not provide the correct model setting for programming the pacer involved. In an effort to prevent unnecessary pacer replacements due to such misunderstandings, Cordis is sending this letter and the accompanying "Instructions for Programming Cordis Pacers" to all users of Programmer III, Model 255A, to supplement and clarify the general instructions provided with the Programmer and the specific programming instructions provided with Cordis pacers.

The capability of each Programmer III unit is controlled by software contained in a memory chip and may be revised by replacing the chip with another containing revised software. To date, four different software revisions have been released for Programmer III, and Programmers with all revisions in current clinical use.

- - -

The specific software revision in each Programmer is readily determined from the Programmer display, as are the pacer models which can be programmed with that software revision. Also, the software provides the menu of programmable parameter values for each model. The new supplementary Programmer instructions explain the programming capabilities of all available software revision levels. Thus, knowing the programmer software revision level from its display, the user can determine from these instructions the pacer models that can be programmed.

Cordis telemetry pacers have a "back-up" mode which is not revealed by telemetry and must be verified by an ECG. The "back-up" mode (V00 at 52.5 ppm) indicates component malfunction or battery depletion and, in such cases, cannot be turned off with the Programmer. The "back-up" mode also has been activated inappropriately by electrocautery, defibrillation, electrical interference, high temperature or connection of a lead. In such cases, the "back-up" mode can be turned off and the pacer reprogrammed to a normal pacing mode. The new supplementary instructions explain which software revisions enable a

Programmer III to turn off the "back-up" mode in these cases and provide the appropriate instructions for each revision level.

Please circulate this letter and the new supplementary instructions to all personnel who use the Programmer III. Then, keep the instructions with the Programmer for ready reference. If you no longer have a Programmer III unit or have any questions about this letter or the new instructions, please call Cordis Customer Service, toll free, at 1: 800: 327-8085 or, in Florida, 1: 800: 432-6565.

HH:mdb

February 21, 1985

Certified Mail - Return Receipt Requested

Norman R. Weldon, Ph.D., President
Cordis Corporation
10555 West Flagler Street
Miami, Florida 33172

Dear Dr. Weldon:

We have reviewed and evaluated all the data for Gamma pacers with protected and unprotected battery cells submitted with the December 21, 1984 and January 30, 1985 letters by Mr. John N. Pagones of your company.

Based on the analysis of reserve cell life test data, pacer life test data, and field performance data, it is our opinion that pacemakers containing polypropylene protected feedthrough batteries from Lots 4280, 4380, and 4480 expose pacemaker dependent patients to the risk of serious adverse health consequences, as a result of early battery depletion (EBD). We recommend that all physicians and hospitals to whom these pacemakers have been distributed be immediately informed of this serious potential problem and any pacemakers not implanted, including those on consignment, be recalled. We request 100% accountability of all Gamma pacemakers containing battery cells from Lots 4280, 4380, and 4480.

Please respond within five (5) days as to what action you intend to take to comply with our request and recommendation. You have an opportunity for consultation under Section 518 of the Federal Food, Drug, and Cosmetic Act (FD&C) on this matter. We believe that this situation presents an unreasonable risk of substantial harm to the public unless corrected in the manner suggested. Notification under Section 518(a) of the FD&C Act is necessary to eliminate this risk and no other provision is available under the Act to eliminate this risk. If you wish to meet with the Center for Devices and Radiological Health on this matter, contact John H. Samalik at 301-427-8110. A meeting will not be necessary if, at this time, you initiate appropriate correction action.

Sincerely yours,

Walter E. Gundaker, Director
Office of Compliance
Center for Devices
and Radiological Health

cc:

Mr. John N. Pagones, Vice President
Corporate Product Assurance
Cordis Corporation
10555 West Flagler Street
Miami, Florida 33172

Mr. Richard Morey, Attorney
Kleinfeld, Kaplan, and Becker
1140 Nineteenth Street, N.W.
Washington, D.C. 20036

Prepared: JSamalik 1/23/85
INit:LJStauffer 1/23/85
draft:RR:1/24/85
Init: Donald Dahms 2/8/85
      WHDamaska 2/11/85
      ABHolt 2/12/85
      WGundaker 2/12/85
Reviewed: Orlando District 2/14/85
t/f:db:2/21/85

cc: HFZ-300 HFZ-321 HFR-41 HFR-4200 HFR-4575 HFC-20 (Shumate) HFC-162
HFZ-70 HFZ-450 HFZ-320 (Moore) HFA-224

FEB 22 1985

Norman R. Weldon, Ph.D., President
Cordis Corporation
10555 West Flagler Street
Miami, Florida 33172

Dear Dr. Weldon:

As you are aware, Cordis is now recalling certain Theta and Gamma series pacemakers because they may have been heat stressed, and have the potential for early battery depletion. These actions were classified by FDA as recalls and assigned numbers Z-059-5 and Z-060-5, respectively.

We understand that Cordis is recalling all heat stressed pacemakers which were manufactured in the United States. However, we also understand that an additional 183 pacemakers were manufactured by Cordis in Roden, the Netherlands, and only 19 of these (those which had not had heat stressed battery cells replaced) were recalled. The remaining pacemakers were apparently shipped back to Roden for distribution, even though the circuitry may have been damaged by excessive heat.

We believe that regardless of whether the heat stressed pacemakers were distributed in this country or other parts of the world, they should all be recalled because of the health hazard involved. We therefore request that you extend your recalls to include all exported pacemakers.

By copy of this letter we are notifying the Government of Netherlands of this situation.

Sincerely yours,

Walter E. Gundaker, Director
Office of Compliance
Center for Devices
and Radiological Health

cc: Mr. John N. Pagones, Vice President
Corporate Product Assurance
Cordis Corporation
10555 West Flagler St.
Miami, Florida 33172

Dr. H. A. M. Suyberbayk, Director
Office of Medicines
Medical Appliances and Infectious Diseases
Ministry for Welfare, Health and Cultrial Affairs
Directorate - General for Health
P.O. Box 439
2260 AK Ludschendam, the Netherlands

TMoore:nh:1/7/85
Init:WHDamaska:1/22/85
Init:ABHolt:1/31/85
init:WEGundaker:2/1/85
T/F:nh:2/6/85

cc:
HFZ-300, HFZ-321/23, HFR-41, HFR-4200
HFR-4575, HFC-20 (Schumate), HFA-224
HFZ-320

February 22, 1985

Director, Orlando District (HFR-4200)

Request for Grand Jury Investigation   Firm: Cordis Corporation
Miami, Florida

Office of Compliance (HFZ-300)
Center for Devices and Radiological Health

Orlando District recommends that the Food and Drug Administration (FDA) request a Grand Jury investigation of the Cordis Corporation to investigate the production and distribution of defective pacemakers and allegations by former employees of the firm that there are safety problems with Cordis products and omission of data from required submissions to the agency, as well as other allegations. The Grand Jury should also determine individual responsibility for any violations of the law (Titles 18 and 21).

HISTORY OF BUSINESS

Cordis Corporation, a Florida corporation established in 1959, is a manufacturer of medical devices with annual sales in FY-84 of over $200 million. The firm is primarily concerned with the development and manufacture of cardiac pacemakers. The firm also manufactures pacemaker leads, angiography catheters, neuroscience products, and accessories. Net sales in cardiac pacemakers alone were $130 million in FY-84. Cordis pacemakers account for approximately 20% of the domestic market and 15% of the worldwide market. The corporation employs approximately 2,200 people in its domestic operation.

INDIVIDUAL RESPONSIBILITY

William P. Murphy, Jr., M.D., Chairman of the Board

Dr. Murphy and Dr. Weldon shared responsibility for the operation of the corporation until September 1984. Since that time, Dr. Murphy has been less active in the day-to-day operations of the firm. Dr. Murphy has been primarily involved in the research and development of Cordis products and public relations with the medical community. It appears Dr. Murphy's role in the operation of Cordis Corporation has diminished over the last several years. During an interview in January 1985, Dr. Murphy stated he had not been involved in the day-to-day operations of the firm for the past 6 or 7 years. Dr. Murphy retired at the end of January 1985 but will continue to act as a consultant to the Board of Directors.

Norman R. Weldon, Ph.D., Chief Executive Officer and President

Dr. Weldon is presently the most responsible individual at the firm. He is at his office on a day-to-day basis and is involved in the daily operations of the firm. He has been president of Cordis Corporation since July 1979. As an example of his responsibility, he stated that he has final authority to approve or disapprove a recall by the firm. Also he is the final authority for approval of product updates before they are issued.

Harold Hershenson, Executive Vice President, and former President of the Angiographic Division

Mr. Hershenson is responsible for Corporate Product Assurance, Regulatory Affairs, clinical research, management information systems, facilities and facilities planning, safety, maintenance of the Cordis Standard Operating Procedures Manual, and he acts as liaison with the plant in Roden, The Netherlands. He directed the Angiographic Division prior to November 1984. Mr. Hershenson reports directly to Dr. Weldon.

John N. Pagones, Vice President, Corporate Product Assurance

Mr. Pagones is responsible for quality assurance and regulatory affairs at the corporate level. Mr. Pagones reports to Mr. Hershenson.

Each of the above officers has represented the Cordis Corporation in meetings with FDA (at headquarters and district levels), with investigators during inspections, and issued instructions to subordinate employees which were carried out. However, our inspections have not established responsibility for potential violations of Titles 18 and 21. Moreover, our inspections have not conclusively established if product defects were the result of overt, deliberate acts or from negligence. We believe that a Grand Jury investigation is necessary to establish the culpability of the various officers for the alleged violations.

ANONYMOUS COMPLAINTS

Between September 1983 and March 1984, the Agency received three anonymous complaints regarding Cordis management, manufacturing procedures, and problems with marketed and developmental products.

1. On November 1, 1983, the Division of Compliance Operations (HFZ-116), Center for Devices and Radiological Health (CDRH), furnished Orlando District an internal Cordis memorandum dated September 21, 1983, subject "Special Audit - Gamma Battery Cell Depletion", which was received anonymously. This document described 134 premature Gamma pacer early battery depletions and included an internal audit of Cordis' manufacturing, testing, and release of Gamma battery cells in use during 1980. Inspection generally confirmed the observations in the internal audit report; however, none of the deficiencies were identified as the specific cause of early battery depletion (EBD).

2. On March 15, 1984, the Division of Cardiovascular Devices, CDRH (HFZ-450), provided Orlando District with an anonymous complaint consisting of an undated letter, postmarked February 29, 1984, along with approximately 26 groups of documents. In summary, this complaint alleged that Cordis Corporation has no sense of moral responsibility or interest in patient safety, and that executive management constantly mandates that inferior products be produced without regard for quality or Federal laws. It suggested that the FDA investigate the firm's Material Review Record (MRR) system and the Model 190A pacemakers which have a "deadly hidden flaw in them." Inspection revealed that Model 190A Omni-Stanicor pacers, and other similar models, had experienced a combination of malfunctions including early battery depletion, reed switch failures, and printed wiring board failures.

3. On March 26, 1984, the Chief, Bioresearch and Monitoring Branch, Office of Compliance, CDRH, (HFZ-341), provided Orlando District with an anonymous complaint postmarked February 28, 1984, which alleged that Cordis' Orthocor Antitachycardia Model 284A pacer was plagued with problems, and was very susceptible to false triggering by electromagnetic interference (EMI) which may result in patient death. The complaint further alleges corporate officials were aware of the flaws and that they had altered test data and changed reports to reflect that the pacer works. This complaint concerns IDE Number G840004 for which CDRH sent a deficiency letter on February 13, 1984. The IDE supplement was deemed approved by CDRH on or about October 1984 because legislative built-in time frames were exceeded. CDRH has requested additional scientific data from the firm. The matter of the Orthocor II Antitachycardia pacer is still under review by CDRH.

INSPECTIONAL FINDINGS

Several inspections were initiated between December 3, 1983, and November 15, 1984, to investigate these allegations and to determine the firm's compliance with the Federal Food, Drug, and Cosmetic Act and regulations. This investigation has revealed the following significant problem areas:

I. Printed Wiring Board Failures

Printed wiring boards are composed of alternating layers of fiber cloth and polyester resin. The board is completely coated with a phenol epoxy. Using a pattern for the particular board desired, copper is layered on the board, holes are drilled through the board, and the board is etched for the appropriate design. There is no epoxy in the holes but copper is sprayed into the holes to plate the surface. The purpose of the holes is to divert electrical pathways around obstacles in the circuitry (e.g., a capacitor). The printed wiring boards are made at 0.018 inch and 0.031 inch thickness.

The failure of Lambda and Theta pacemakers due to defects in the printed wiring boards was investigated during inspections of April 16 - May 15, 1984, and May 22 - June 5, 1984.

Inspections revealed that certain Lambda and Theta series pacers had malfunctioned because of failure of the printed wiring board and this malfunction had resulted in sudden "no-output" failure. The failures occurred in pacers equipped with a printed wiring board with unfilled plated through holes and a crimped D-cell battery. The firm determined that the battery gave off dioxolane vapor which was absorbed by the printed wiring board. This caused the board material to expand, causing the copper layer in unfilled plated through holes to crack. The flow of electricity stopped when the crack went completely around the hole, causing a sudden no-output failure. This failure mechanism is peculiar to the 0.031 inch thick board. Why this failure mode involves only the 0.031 inch thick board has not been investigated by the firm.

A sudden "no-output" failure of these pacers could have an adverse health consequence, particularly to pacer dependent patients. Such a sudden failure would cause the heart to beat at its intrinsic rate, probably as low as 35 to 40 beats per minute in a pacer dependent person, which in turn could result in cardiac arrest.

The inspections revealed there were at least 809 pacer failures worldwide due to the printed wiring board failures. These failures occurred in Models 221A and 221B (Theta series) and 190A, 190E, 208A, 215A, and 188B7 (Lambda series). The largest number of failures, 690, occurred in the Lambda Omni-Stanicor Model 190A. Also, there were other models subject to this failure mode (crimped D-cell battery with open plated through holes in the printed wiring board) in which no failures have been reported. These were Lamda Models 235A, 235B, 236A7, 236B7, 238B7, and 241.

On September 22, 1980, the firm issued a modification to the manufacturing procedure (Documentation Change Notice #16244) which called for filling all unfilled plated through holes in all printed wiring boards with solder. This modification appears to have corrected this problem. However, at the time of this change there were approximately 2,200 Lambda and Theta pacers in finished goods stock with unfilled plated through holes. Instead of reprocessing these pacers to correct the defect, the firm, reportedly based on review by a PET, decided to distribute the pacers without correcting them (Documentation Change Notice #16244 states "use up finished goods inventory"). These pacers were distributed between September 1980 and August 1983.

In discussing this situation on May 14, 1984, with Norman R. Weldon, Ph.D., president of the firm, he stated it was common knowledge throughout the electronics industry that plated through holes in printed wiring boards must be filled. When he found out that such holes were not being filled, he ordered them filled. He said at that time there was no discussion of a recall or physician notification. He also said if someone had recommended that finished pacers in inventory be reworked to fill any unfilled holes, he would have approved that recommendation.

Between August 15, 1979, and April 1984 the firm issued Technical Memoranda and Product Updates regarding this situation. In letters to the firm dated September 7 and October 22, 1984, the Center for Devices and Radiological Health requested that the firm send notification letters to physicians concerning the printed wiring board failures. At a meeting with CDRH on September 19, 1984, representatives of the firm (Weldon, Hershenson, and Pagones) refused to issue a notification to physicians saying the Technical Memoranda and Product Updates are sufficient notice to physicians and the medical community. By letter dated December 6, 1984, the agency advised Cordis that product updates and technical memoranda are not adequate to alert physicians of the potential problem. The firm was requested to notify physicians of this problem by an appropriate notification. By letter dated January 25, 1985, from the firm's attorney, Richard J. Morey, the firm agreed to issue a safety alert on this problem. The draft "Dear Doctor" letter is being reviewed by CDRH.

Two samples were collected to document the shipment of uncorrected pacers subsequent to September 22, 1980, when the firm began filling the holes:

1. DOC 84-374-546 - Documents the shipment of thirteen (13) Model 190A pacers from October 9, 1980, through February 13, 1981, to various consignees.

2. DOC 84-374-547 - Documents the shipment of a Stanicor Theta, S/N 221B7-8999, to Columbia Regional Hospital, Columbia, Missouri, which was invoiced on March 5, 1982. The pacer was implanted on February 25, 1982, and explanted on August 24, 1983, because of no output. Analysis revealed the printed wiring board had a cracked plated through hole. This pacer was shipped after the firm began to fill the open plated through holes in pacers on the production line.

II. Heat-Stressed Pacers

During the inspection of April 16 through June 26, 1984, an FDA investigator learned that a Cordis Model 233F Sequicor II pacer failed 3 months after implant. The pacer had been subjected to a high temperature of approximately 115° C (239° F) during a gas analysis procedure. This failure was investigated during the inspections of July 23, 26, 30, and 31; August 3, 6, 10, and 16, 1984; and September 14, 16-21, 27, October 1-3, 5, 9, and 10, 1984.

The investigation revealed that some pacers have been subjected to high heat, reworked, and then implanted, some with the original batteries and some with batteries replaced. One Gamma and one Theta pacer are randomly selected each week as weld qualification and gas analysis samples. The gas analysis involves preconditioning by holding the pacer in an oven at 115° C for up to 24 hours (in one case a pacer was held for 65 hours). The pacer housing or can is punctured and the internal moisture is determined. The can is then cut open and the weld is examined. Following the weld examination the pacer may be reprocessed and the batteries and circuitry may be salvaged rather than scrapped or they may be replaced.

Gamma pacers utilized for gas analysis were first preconditioned at a temperature of 115° C in March 1980 after initial qualification disclosed no problems. Prior to August 1980 the Gamma battery was reportedly routinely replaced. Reportedly, the firm did not replace the Gamma battery between August 1980 and April 1982. In April 1982, the firm again began replacing the Gamma battery in gas analyzed pacers and continued this practice until a problem was discovered. Because quality control personnel were not consistent in their rework procedures, it is difficult to document which pacers did or did not receive replaced Gamma batteries. Cordis has provided conflicting data and failed to document the exact dates or reasons for these changes.

According to the firm, Theta pacers were preconditioned at 37° C prior to March 1983. Since the battery could tolerate that temperature without adverse effects there was no need to replace the battery. An undocumented change occurred on March 27, 1983, when the laboratory began heating the Theta pacers to 115° C, in spite of the fact that the engineering specification states these batteries should not be held at ambient temperatures exceeding 54.5° C (130° F). The decision to increase the preconditioning temperature was made by Harold Hershenson. Reportedly, this change was not communicated to production personnel. Therefore, production failed to replace the battery in heat-stressed pacers until they became aware of the change on December 5, 1983.

The reprocessed pacers were placed in finished goods inventory and distributed, some with original batteries which were exposed to 115° C temperatures for extended periods, and some with replacement batteries. A total of approximately 254 pacers were gas analyzed and exposed to this high temperature; 225 Gamma pacers and 29 Theta pacers. A few of these pacers with heat-stressed batteries were distributed through June 1984, or up to 6 months after learning of the problem in December 1983.

Pacers Analyzed at 115° C
(as of December 8, 1983)

Total Pacers	Pacers Sold	Cells Replaced		Cells Not Replaced	
		Implanted	Explanted	Implanted	Explanted
254	179	97	11	64	7

The firm failed to validate the above-described process and had no documentation of the affect heating to 115° C would have on the pacer components. Also, there was no written procedure for conducting the gas analysis, including the preconditioning or reprocessing of these pacers. The oven used to precondition the pacers was never validated and the actual temperatures reached during the heating operation were rarely recorded. Sometimes the temperature may have exceeded 115° C.

Three samples were collected to document the pacers exposed to the 115° C temperature prior to gas analysis:

1. DOC 84-268-852 is Model 233F-9549 Sequicor II Theta pacer, shipped to the University of California, on or about July 29, 1983, and implanted with the original batteries which were subjected to 115° C temperature. The pacer failed three (3) months after implant and it was explanted and returned to Cordis Corp. Analysis of this pacer by Cordis revealed that the Pellon (polypropylene) separators in the battery cells had melted, apparently allowing the anode and cathode in the negative cell to come in contact and short the battery.

2. DOC 85-374-555 is Model 233F-08046 Sequicor II which was shipped to a Cordis salesperson at Louisville, Kentucky, on July 29, 1983, but retrieved before implantation. Analysis by the firm revealed the Pellon separator in both cells of the battery showed evidence of "slight melting in both cells."

3. DOC 85-374-556 is Model 333D7-4181 Stanicor (Gamma) pacer which was selected for gas analysis on November 17, 1982, and was analyzed on November 19, 1982. On May 8, 1984, the "use before date" was extended to August 1985. On June 26, 1984, the pacer was shipped to Memorial Hospital, Indiana. This sample documents that the firm distributed heat-stressed pacers with replaced batteries.

The firm began replacing all batteries in gas analyzed pacers on December 5, 1983. Now, only the hybrids are salvaged.

The firm has issued a notification to physicians and hospitals of the potential problem with these pacers and has recalled any domestically manufactured pacers exposed to gas analysis which were not implanted [recalls Z-059-5 (Theta models) and Z-060-5 (Gamma models)].

During these inspections FDA learned that Cordis also performed gas analysis on 183 pacers manufactured at the firm's plant in Roden, The Netherlands. The firm claims that the Roden plant replaced all batteries in heat-stressed pacers except for 19 pacers which contain their original battery. Cordis has included these 19 pacers in the recalls. However, the firm has refused to include in the recall the 164 Roden manufactured pacers exposed to high temperature and which have replaced batteries. Pacers with replaced batteries are included in the recall of domestically manufactured pacers.

From the above it appears that Cordis Corporation did not appropriately control the gas analysis and reprocessing of pacers exposed to 115° C temperatures. The laboratory made a change in the temperature at which pacers were preconditioned without adequate written authorization and subsequently failed to communicate that change to appropriate personnel. The result was "business as usual," in that some batteries which might have been adversely affected by the higher temperature were not replaced and were implanted.

The decision to increase the temperature at which pacers were preconditioned was made by Harold Hershenson, Executive Vice-President, on March 5, 1980. The decision to salvage or scrap batteries exposed to the elevated temperatures was not consciously made by management since the increase in the test temperature was not communicated to production personnel and there was no change on the production line. There is no evidence that other officers were aware of these decisions.

III. Charity Pacers

On June 5, 1984, an FDA investigator visited the office of M.D., Miami, Florida, to perform a recall effectiveness check on recalls Z-064/067-4 (Gamma pacers recalled due to early battery depletion). The investigator learned that one pacer, Cordis Omni-Stanicor (Gamma) S/N 334A-7127, had been donated as a "charity" pacer by the Cordis Corporation. The physician was aware that the pacer was "slightly out-of-specification" and because of this the pacer was not covered by the warranty. This particular pacer had been implanted on April 15, 1982, in a patient who was a "charity case," who returned to his home in Guatemala following recovery from the surgery.

The issue of "charity pacers" was covered during inspections of the Cordis Corporation on July 23, 26, 30, 31; August 3, 6, 10, and 16, 1984; and October 3-5, 1984.

The inspections disclosed that it was Cordis practice to donate pacers to physicians for implantation into patients outside the United States who could not afford to pay for the pacers. This practice was initiated in January 1982 by Dr. Weldon, according to Richard A. Smolowitz, Manager, Quality Assurance Implantables. Typically the pacer was "minimally out of specification" in one acceptance criteria and was not covered by the usual warranty. When a pacer was found to be minimally out of specification the device history record (DHR) was marked to indicate the pacer should be scrapped. The unit and the DHR were forwarded to a Project Engineering Team (PET) for a determination as to the disposition of the pacer. If it was decided that the pacer was a candidate for donation the DHR and the Material Review Record (MRR) were marked "for charitable implant." On the MRR this statement is usually followed by "(N. Weldon requirement)." The pacer was then stored with other charity candidates to await a request for a charity pacer from a physician.

In numerous instances the final disposition of the pacer could not be determined. Review of records by our investigators and the firm indicates that 74 units have been dispositioned as "charity" candidates. Of these, 30 were actually distributed to physicians, one of which was returned to Cordis for unknown reasons (see DOC 84-268-851). Of the 29 donated pacers, 9 were minimally out of specification, 10 had their "use before date" (UBD) extended, and 10 had passed their UBD. The firm could not account for the disposition of the 43 remaining pacers initially earmarked as scrap for possible charity donations. The firm has no written procedure describing the criteria for "minimally out of specification" pacers which may be dispositioned for donation to charity.

The firm has agreed to a CDRH suggestion to recall all charity pacers which have not been implanted and to assure each physician has been notified of the out of specification status of each implanted unit. The firm has not yet issued the recall letters.

Sample DOC 84-268-851 documents the donation of a charity pacer. This Multicor Gamma pacer, S/N 337A-8554, was subjected to final electrical testing on October 14, 1981. The pacer was found to be out of specification for Haversine Sensitivity (the specification is not less than 4.5 at 40 Hz, while the test result was 4.6) and was dispositioned as a charity candidate. On or about April 5, 1983, this pacer was donated to M.D., , Florida, for charitable implantation. Approximately one (1) month later, Dr. returned the pacer to Cordis without explanation. The pacer was eventually shipped to an unnamed dog testing facility in North Carolina.

IV. Extension of "Use Before" Date

The "use before date" (UBD) is the latest allowable date for implantation, calculated from the month of power source installation. The firm had between 500-600 Model 333D7 pacers which it intended to export to foreign countries as the pacers were nearing the UBD. The engineering specification for calculation of the UBD (#9510031) allowed for an extension of 18 months provided the pacer met all test parameters when retested. However, rather than do all of the testing required by specification #9510031, the firm initiated three Temporary Authorities (TA's) which eliminated the requirement for meeting all final electrical test parameters on these 500-600 pacers. Reportedly, the first T.A. (#79867), approved in December 1983, was impossible to do since the test was to be accomplished without opening the package and reportedly no pacers were tested under this T.A. The two remaining TA's were requested by Stephen F. Vadas, Ph.D., Manager, Regulatory Affairs, and approved by the PET team in April 1984, and June 1984. These

TA's abbreviated the requirements for extension of the UBD tests for the pulse interval and an x-ray for depleted batteries. On the basis of a determination that the pulse interval was within the acceptable range and the battery was not depleted, the UBD of these 500-600 pacers was extended to July 1985 ("use before August 1985"). Approximately 30 of these pacers were initially designated as early battery depletion pacers following the initial x-rays. The firm revised its specification for extending the UBD in 1984 and permitted extension of 24 months. However, the pacers in question were extended as long as 32 or 33 months. Although these 500-600 pacers were intended for export only, our investigation has disclosed that the pacers were also distributed domestically and a few of these were dispositioned as "charity pacers."

The abbreviated tests used to extend the UBD in TA 70736 and TA 70736A was not validated as an appropriate procedure to extend the UBD and theoretical calculations of battery life were not conducted on any of these pacers after the firm decided to extend the UBD.

Sample DOC 85-374-556 documents a pacer with an extended UBD. This Stanicor Gamma pacer, S/N 33307-4181, was manufactured in November 1982. On November 17, 1982, this pacer was selected as a weld qualification sample and was subjected to gas analysis on November 19, 1982. The final testing was accomplished on December 16, 1982, and the pacer was released on December 27, 1982, with a "use before date" of June 1984. On May 8, 1984, the use before date was extended to August 1985 and the pacer was released again on May 10, 1984. On June 28, 1984, the pacer was shipped to hospital Indiana, and presumably was implanted.

V. Polypropylene/Polyimide Protected Feedthroughs

Inspections from December 3, 1983, through May 18, 1984, revealed that in November 1979, Cordis Corporation submitted a 510(k) premarket notification for Gamma series pacers that contained a hermetically sealed lithium/cupric sulfide battery. Each pacer contains one battery, each made up of two gamma cells. The cell has a positive lead (feedthrough pin) which passes from the inside to the outside of the cell through a glass feedthrough, which insulates the positive lead from the cell container, which acts as the negative terminal.

In June 1980, testing by the firm uncovered corrosion and low resistance in the glass feedthrough. Corrosion of the glass was creating a lithium bridge between the anode and cathode permitting an electrical short, thereby depleting the battery of its energy. Usually, one cell depleted and this caused the pacer to malfunction. In October 1980, in an effort to solve the corrosion problem, the firm changed the Gamma cell manufacturing procedure and added the application of a polypropylene sleeve to the glass feedthrough to protect it from elctrolyte attack. The polypropylene was replaced by a polyimide coating in May 1982, because it reportedly afforded better glass protection and was easier to apply.

In October 1980, when the firm began applying polypropylene to the glass feedthrough, the firm had approximately 6,000 pacers with Gamma cells with unprotected glass feedthroughs in finished stock or in the process of being manufactured. These pacers were not reworked to add polypropylene protection but rather were distributed "as is" through August 1983. There is no evidence that suggests that corporate officers were aware of the potential for early battery depletion in Gamma cells with unprotected feedthroughs in 1980. However, there was information available to them that, if properly evaluated, could have prevented distribution of pacers with cells with unprotected glass feedthroughs. This information was in the form of a study of 200 Gamma cells initiated by Cordis in October 1980 and discontinued in October 1982. This study showed the mean time to failure of Gamma cells with unprotected feedthroughs was 32 months. However, the study was not evaluated until July 1983.

On May 15, 1985, at the conclusion of the April 4 through May 15, 1984 inspection, management professed embarassment that the 200-cell study had not been evaluated in a timely manner. Harold Hershenson, Executive Vice President, said that had the study been evaluated sooner, a decision may have been made to rework the pacers with unprotected feedthroughs in finished stock rather than continue distributing them "as is."

When the firm began receiving a significant number of reports of pacer failures due to early battery depletion in mid 1983, a decision was made to issue a notification on the pacers with batteries with unprotected glass feedthroughs (recalls Z-064-067/4). This notification extends through battery lot number 4180, approximately half of which have unprotected feedthroughs and half of which have polypropylene protected feedthroughs.

The firm has submitted data which shows that battery lots 4280 and 4380 (the first complete lots with polypropylene protection) were incorporated in 1,174 implanted pacers. Of these 45 have failed, 36 due to early battery depletion. Also, there have been a total of 168 failures of pacers with battery lots 4280 and later, of which 51 were due to early battery depletion. Therefore, CDRH has prepared a letter requesting Cordis to issue a notification on pacers with batteries containing cells from the first three lots with polypropylene protected feedthroughs (battery lot numbers 4280, 4380, and 4480). The letter has not issued to Cordis yet.

DOC 84-374-482 documents the July 27, 1982, shipment of Omni-Stanicor (Gamma) pacer, S/N 334A-11141, containing cell feedthroughs which are protected by polypropylene. Cordis began coating the feedthroughs with polyimide on May 19, 1982. However, pacers which were in the process of assembly or which were in finished goods inventory were not reworked but were distributed.

DOC 84-374-484 documents the sale on January 14, 1981, of an Omni-Stanicor (Gamma) pacer, S/N 334A-03078 which had battery cells with unprotected glass feedthroughs. This pacer was delivered to Hospital, in ., Texas, even though Cordis began protecting the feedthrough with polypropylene in October 1980.

VI. Failure to Submit 510(k) Notification, Premarket Approval Applications, and Supplements

In several instances Cordis Corporation made a decision that it was unnecessary to advise FDA of changes in procedures or manufacturing operations by submissions of 510(k) notifications, PMA's or supplements. The following are pacers which were marketed or modified and which were not reported to the agency as required:

A. Multicor Gamma Model 340A (Mini-Gamma)

The firm began distribution of this pacer in February 1981 without submission of a 510(k) notification. The firm has sold 495 Model 340A pacers domestically and 361 in foreign countries. The firm did not feel this pacer was significantly different from other Gamma models to warrant notifications. 510(k)'s had been previously submitted on Gamma Models 336A, 336B, and 337A. The primary difference between the models is that the 340A is smaller and has a battery which is approximately 50% the size and capacity of the other Gamma pacers.

In a letter to John C. Villforth, Director, CDRH, dated September 17, 1984, signed by Mr. Weldon and Mr. Hershenson, the firm agreed to discontinue distribution of the Model 340A pacer until a 510(k) notification was approved. This was confirmed in a letter to William Damaska, Director, Division of Compliance Operations, CDRH, from Mr. Hershenson dated September 20, 1984. By letter to Norman R. Weldon, President, dated January 29, 1985, Walter E. Gundaker, Director, Office of Compliance, CDRH, requested that all Mini-Gamma pacers which are on consignment and/or are not implanted be returned to Cordis.

Distribution of this pacer is documented by sample DOC 84-374-485.

B. Stanicor Theta Models and Omni-Stanicor Lambda Models

On September 22, 1980, the firm decided to fill plated through holes in printed wiring boards with solder in order to correct sudden "no-output" failures in Theta and Lambda pacers. (See heading "I. Printed Wiring Board Failures".) The firm never submitted this modification to the FDA by means of a 510(k) notification.

C. Gemini 415A and Sequicor 233F Pacers

From June 1984 through September 1984, the firm changed the formulation of the polyimide material in use by diluting the polyimide with additional solvent. This "diluted polyimide" was then applied to glass feedthroughs of Theta 1/4 Pi cells. The diluted polyimide was developed to reduce the viscosity of the material so that void formation during curing would be reduced. Reportedly, approximately 3,000 cells were manufactured using lids that had the diluted material applied in either single or double coating operations. These cells were used in manufacturing and distributing 984 Model 233F Sequicor II and 589 Model 415A Gemini pacers. These pacers were manufactured even though PMA supplements were not submitted to FDA describing the formula change and even though the firm had been advised of the significance of feedthrough changes in 1983 and 1984. In fact, they had been requested to submit a retrospective 510(k) notification on feedthrough changes in December 1983.

D. Polypropylene/Polyimide Protected Feedthroughs

Inspections of the firm disclosed the firm was experiencing early battery depletions in Gamma pacers with hermetically sealed, lithium-cupric sulfide batteries. The firm issued a notification on December 5, 1984, for approximately 11,000 Gamma series pacers with batteries manufactured between November 1979 and October 1980. The notification issued because of early battery depletion associated with self-discharge due to corrosion of the glass feedthroughs (recalls Z-064-4 through Z-067-4). In October 1980, the firm modified the feedthrough to include a polypropylene insulator designed to protect the glass from electrolyte attack. The feedthrough design was changed again in May 1982 and consisted of replacing the polypropylene with a polyimide coating because reportedly polyimide was easier to apply and afforded better protection than polypropylene.

Cordis Corporation had submitted a 510(k) premarket notification on the original Gamma pacer without cell feedthrough glass protection. However, the firm failed to submit updated 510(k)'s covering the polypropylene or polyimide protection until requested to do so by CDRH on December 7, 1983. The firm finally submitted the requested data on April 4, 1984, and Equivalence Summary #K841414 on June 5, 1984. These documents are currently under review by CDRH.

VII. Possible Obstruction of FDA Inspection

FDA inspection of January 17 - April 2, 1984, revealed that Cordis formed a task force to investigate the problem of early battery depletion in Gamma series pacers. On December 3, 1983, the FDA investigator requested a copy of the task force assignment. On December 7, 1983, he was given a one-page memorandum by Mr. Pagones, entitled "Gamma Cells and Gamma Pacers - Task Force" dated August 19, 1983, and signed by John N. Pagones, Vice President, Corporate Product Assurance. The memo was addressed to members of the task force and other management people.

On January 24, 1984, the investigator was told by Frank Gregorio, Senior Regulatory Affairs Coordinator, that the original assignment memorandum issued by Mr. Pagones was a two-page memorandum dated August 19, 1983. The investigator was furnished a copy of the two-page document by Mr. Gregorio, reportedly on the instructions of Mr. Pagones. The original memorandum listed eight areas which the task force was directed to consider and investigate. These eight points had been deleted from the memo copy given the investigator in December 1983.

Our investigation of this matter revealed that Mr. Pagones had "revised" his original memo on or about December 1, 1983, after the task force had completed its investigation. Mr. Pagones revised the memo on his own initiative. There is no evidence that higher management instructed him to revise the memo or in fact knew of the revision until after the fact. Mr. Pagones stated that he "abbreviated" the original memo to general terms to emphasize the primary purpose of the task force, i.e, to define and to determine the cause of the problem.

We believe Mr. Pagones' purpose in not providing the original assignment memo was to obstruct the FDA investigation of early battery depletions in Gamma series pacers and, therefore, charges under Title 18 (1001 and 1505) should be considered.

VIII. Model 284A Orthocor II Antitachycardia Pacer (IDE 840004)

An anonymous complaint was received on March 5, 1984, by the Center for Devices and Radiological Health alleging the firm was experiencing severe problems with this pacer. The complaint stated management was aware of the problems and had altered test data and changed reports to indicate that the pacer works.

The inspection of this device was made on June 20, July 3, 9-13, 17-20, 31, and August 1-3, 6, 7, and 10, 1984.

The inspection failed to confirm that test data and reports had been altered in any way. The inspection did reveal that some statements in the IDE application were not completely accurate. For example, in reporting the results of tests in dogs the report states that there were no episodes of atrial or ventricular fibrillation even during deliberate attempts to stress the dog's ventricle. However, the firm's records show that a dog tested at the Massachusetts General Hospital, Boston, Massachusetts, experienced several episodes of ventricular fibrillation. Also, the application states that the circuit assemblies met life test requirements. The circuit assemblies were not tested in accordance with the test protocol and some of the circuit assemblies did not meet specifications (two assemblies were out of specifications in 43 parameters). Two pacers failed the defibrillation test yet the IDE application states that pacer parameters were unchanged after defibrillation testing. The IDE application dated January 18, 1984, further states there were no safety problems and "the software programs met test requirements." The qualification of the pacer software was not actually completed until July 9, 1984.

IDE 840004 was deemed approved in October 1984, and CDRH has requested additional scientific data from the firm. The matter of the Orthocor II pacer is still under review by CDRH.

IX. Compliance With CGMP's

Inspections of the Cordis Corporation in 1974 and 1975 revealed deficiencies which demonstrated that the firm's operations were not in a state of control. In 1975, the FDA recommended an Injunction in order to prevent adulterated devices from reaching the marketplace. The Court appointed a Special Master to review the facts concerning the firm's manufacture of pacemakers. The Special Master advised the Court that corrections were necessary in the following broad areas:

A. Component specifications and engineering inadequacies.

B. Inadequacies in formal documentation of manufacturing and inspectional procedures.

C. Inadequacies in the control of procured components and materials.

D. Inadequacies in product identification and configuration management.

E. Inadequacies in traceability, test integrity, and the information system.

F. Inadequacies in material review board and waiver procedures.

G. Inadequacies in statistical sampling and testing procedures.

H. Inadequacies in the calibration, operation, and maintenance of manufacturing equipment.

I. Inadequate housekeeping and the failure of employees to follow formal internal Cordis procedures.

Inspections since 1975 have revealed GMP deficiencies which appeared to be isolated instances and not the routine practice of the firm.

An in-depth inspection to evaluate the firm's current compliance with CGMP regulations was undertaken between October 12 and November 15, 1984. This inspection was accomplished by Orlando District investigators along with personnel from WEAC, CDRH, and ORO. The inspection disclosed that while deviations from regulations existed, the firm appeared to be in overall compliance. However, the inspection found that significant deviations from CGMP regulations existed in battery manufacturing in many of the same areas delineated by the Special Master in 1975. Because of corrections made and the interim response by the firm, an FDA Ad Hoc Committee, meeting on December 5, 1984, decided not to pursue an injunction on current GMP deficiencies but to reinspect in 3 to 6 months.

Since the current investigation began in December 1983, we have been evaluating the firm's compliance with GMP's which were in effect since 1978. In this review we have observed one deficiency which stands out and has an effect throughout the operation at Cordis, which is the use of the Project Engineering Team (PET), Material Review Committee (MRC), and the Material Review Board (MRB). The PET, MRC, and MRB are committees set up to review discrepant materials, referred to them by a Product Quality Team, which do not meet specifications and to decide on their disposition. The decision may be to scrap, use as is, or change a specification or procedure to fit the situation.

In using this committee system, executive management has relinquished control for making critical decisions to these groups of engineers and lower-level managers. The decisions made by the PET, MRC, and MRB do not require formal executive management review. In fact, executive management awareness of these decisions is not documented. The decisions made by the PET, MRC, or MRB are put into effect immediately and reportedly are not reviewed at any higher level of management. The only review occurs if the members of a PET cannot concur on disposition of material. The review process would then move to the next higher level, the MRC. If the members of the MRC cannot concur on disposition, the decision would then go to the MRB. The decisions and the reasons for the decisions are poorly documented and in some instances are not documented.

An example of this was the apparent decision to distribute approximately 2,200 Lambda and Theta pacers in finished goods inventory containing printed wiring boards with unfilled plated through holes, after a decision was made to fill all plated through holes with solder.

Another significant deficiency is in the area of review and evaluation of complaints. Inspections of April 16 - June 26, 1984; and July 23, 26, 30, 31, August 3, 6, 10, and 16, 1984, revealed that not all complaints received by the Cordis Corporation are reviewed, evaluated, and maintained by the formally designated complaint file unit.

Throughout this investigation, the investigators had been evaluating the firm's normal complaint handling system and the generation of complaint forms (Product Service Reports or PSR's). On June 12, 1984, the investigation revealed that a number of complaints, in the form of lawsuits or notifications of intention to sue, were being maintained in the legal department and were not receiving the kind of review, evaluation, and follow-up contemplated by the regulations.

On June 12, 1984, Frank Gregorio, Senior Regulatory Affairs Coordinator, was asked by the investigator to provide a listing of all lawsuits involving product failure or alleged failure. He provided the investigator a list of 49 complaints being maintained by the legal department which had not been handled through the normal complaint system and PSR's had not been completed for them. By June 15, 1984, PSR's had been completed for 22 of the 49 complaints. On August 10, 1984, the investigator requested that Mr. Gregorio allow the review of the source documents on a specific complaint (PSR D-619) which was on file in the legal department. Mr. Gregorio responded that the legal files were confidential and he could not allow review of this file.

During the recent GMP inspection of October 12 through November 15, 1984, an FDA investigator again requested review of the complaints on file in the legal department. Mr. Hershenson stated that a general review would not be allowed since the files were not considered source documents by Cordis. On October 24, 1984, John Pagones gave the investigator a letter dated October 24, 1984, and signed by Daniel G. Hall, the firm's General Counsel, which stated that selected source documents would be provided to FDA.

On November 2, 7, and 13, 1984, the source documents for 59 complaints on file in the legal department were provided to the investigator. None of these complaints had been processed through the normal complaint system and neither a PSR nor a normal follow-up had been accomplished at the time we became aware of the complaints in June 1984. The firm has now reportedly completed abbreviated Product Service Reports on these 59 complaints. In many cases the PSR is incomplete (e.g., lacks model number) or the PSR contains information that is not in the source document(s). The complaints involved injuries, hazards, and deaths, due to failures of pacemakers, leads, catheters, and other devices. The incidences complained of occurred between 1975 and 1984.

Cordis (Frank Gregorio, Harold Hershenson, and Daniel G. Hall) have refused to allow FDA investigators to review the legal files in general or the complete files for the specific complaints identified to FDA. The documents provided to FDA do not always contain necessary information to evaluate the complaint or to determine the firm's evaluation of the complaint.

Our review of the complaint system at Cordis reveals it to be inadequate. A Grand Jury investigation should determine:

1. That all complaints have been properly handled and evaluated.

2. That each complaint has been furnished to FDA.

3. Whether complaint information was intentionally withheld from FDA as alleged by employees of the firm.

INTERVIEWS WITH CURRENT AND FORMER EMPLOYEES

Orlando District has interviewed several current and former employees of Cordis Corporation. These individuals may be potential witnesses before a Grand Jury. The individuals interviewed are listed below along with a short summary of the information given to FDA Investigators.

1.

[employee] was interviewed by Orlando District personnel between September 17 and 20, 1984, at

. This interview resulted in taking an extensive affidavit from [employee] in which alleges a number of potential problem areas. Some of the allegations were confirmed during our inspections, some were unconfirmed, and others were not investigated due to time and resource constraints. The most significant allegation that was not investigated concerned Sequicor, Gemini, and Multicor 402 pacers having a problem with a shortened end-of-life indicator due to a combination of defects in the electronics of the pacer.

[employee] employed by the Cordis Corporation

began employment as an

Associate Regulatory Affairs Coordinator, and after 1 year he was promoted to Regulatory Affairs Coordinator. Reportedly , duties included the coordination of submissions of Premarket Approval Applications (PMA), Investigational Device Exemptions (IDE), and pre-market notification submissions [510(k)]. His submissions were routinely reviewed, and sometimes modified, by Joseph J. Schwoebel, Manager, Regulatory Affairs, John R. Pagones, Vice President, Corporate Product Assurance, and possibly others.

[employee] alleges that Harold Hershenson, John Pagones, and Joseph Schwoebel were aware of the intentional falsification, manipulation, and omission of data submitted in support of PMA's, IDE's, and 510(k)'s. stated that in view, it was company policy to use deceptive practices in order to hide information or mislead the FDA. said this attitude was caused by the highly competitive market pressures in the pacemaker industry. Some of these practices included omission of unfavorable test data, omission of findings from reports, and failure to perform all qualification testing but stating it had been done.

[employee] has stated complained about inaccuracies in Temporary Authorities, Documentation Change Notices, and FDA submissions; yet was forced by Mr. Pagones and Mr. Schwoebel to sign them when was threatened with loss of his job. Also, was told to not file supplements to PMA's and 510(k) notifications when knew they were required to cover changes in the products.

[employee] has offered to review any PMA, IDE, or 510(k) notification which was involved with while employed at Cordis Corporation for the purpose of identifying false data, statements where has knowledge of omitted data, and data intended to mislead a reviewer.

2. [Cordis Employee] is currently employed by the Cordis Corporation as a Senior Regulatory Affairs Coordinator. [employee] is a former FDA Investigator.

On August 27, 1982, [employee] visited the Miami Resident Post office and had a short discussion with FDA employees, (CSO Jeanne Bush and Clerk-Typist Lourdes Perez Trujillo), telling them of problems had encountered at the firm. said the firm was relustant to reject incoming raw materials that did not meet specifications. stated that often specifications were revised and broadened so that the material would pass inspection. According to [employee] , verbal complaints may not be recorded and some written complaints were not filed in the complaint system.

We have not attempted to interview [employee] outside of a statutory inspection since is a current employee of the firm, and since we feel would refuse to discuss the firm or answer questions. However, [employee], as a Regulatory Affairs person, has attended internal meetings and could testify before the Grand Jury on responsibility of individuals and how decisions are reached on regulatory matters.

3. [Cordis Employee], former manager, Regulatory Affairs, was interviewed by telephone on January 9, 1984, and April 10, 1984. Mr. [employee] last known employer was Teletronics, Denver, Colorado, a pacemaker manufacturer. An FDA investigator was told by [employee] that Mr. [employee] had left Teletronics for employment with a firm known as Pacesetter, somewhere in California. However, this information has not been confirmed. A number of areas were discussed concerning Cordis' operations. Mr [employee] made several allegations including that the firm was aware in mid-1980 of the glass feedthrough corrosion which led to early battery depletion in Gamma pacers; the alteration of the Gamma Task Force assignment memo by Mr. Pagones; and that the firm gave incomplete and inaccurate information to FDA.

Unknown to the investigator, the telephone conversation of April 10, 1984, was tape recorded by Mr.[employee]. We learned later that he played the tape back to an unidentified person, currently employed by Cordis, who reported the conversation to Cordis executive management. Mr. [employee] also reported selected portions of the conversation to Dr. Weldon and [employee].

4. We believe other current and former employees can be subpoenaed to testify on their knowledge of decisions, Cordis procedures, and responsibility.

CORDIS RESPONSES

Cordis management has stated that decisions made on the design and marketing of the products initially, as well as the changes instituted afterward, were made with the current state-of-the-art technology. They maintain that hindsight should not be used in evaluation because the problems were not evident but developed over a period of time. They contend that the unprotected glass feedthrough problem constituted state-of-the-art technology that could not be prevented. Cordis management believes that the polypropylene and polyimide corrections have solved the feedthrough degradation problem. In general they maintain that the firm strives to comply with Agency regulations and GMP's.

Cordis has submitted seven written responses during our investigation. On June 1, 1984, Cordis representatives presented a written response dated May 31, 1984, to District personnel in Orlando. The response consisted of two volumes of documents, speaking to GMP's and other violations and their correction, or disagreement with FDA-483 observations relating to the Gamma pacers.

The second response dated June 2, 1984, was presented to Miami Resident Post personnel. This document contends that pacers containing cells with polypropylene protected glass feedthroughs are safe and effective.

The third response, dated June 29, 1984, relates to polyurethane leads and FDA-483's presented on April 6 and May 15, 1984; and the to FDA-483 presented on April 27, 1984, relating to angiographic catheters. With respect to polyurethane leads the firm's response states they do not consider surface cracking is a significant risk about which physicians should be notified. The issues regarding all polyurethane leads are under consideration by a CDRH task force. With respect to the six observations on angiographic catheters, the response described steps being taken to correct the deficiencies.

The fourth response is dated August 9, 1984, and responds to the FDA-483 presented on June 5, 1984, covering the inspection concerning failure of printed wiring boards in Lambda and Theta pacers. The response states that although the firm decided to fill unplated through holes with solder, finished goods were not reworked because the failure rate was low.

The fifth response dated October 22, 1984, covers the inspection of June 20 to August 10, 1984, which was an IDE inspection of the Model 284A Orthocor II, antitachycardia pacer. The IDE has been deemed approved.

The sixth response was dated November 30, 1984, and is an interim response to the FDA-483 presented at the conclusion of the October 12 to November 15, 1984, GMP inspection. The response briefly outlines corrections which have or will be made to correct GMP deficiencies. A detailed response to be submitted at a later date is promised.

The seventh response is a voluminous document and is the detailed response promised regarding the FDA-483 issued at the conclusion of the most recent GMP inspection of October 12 to November 15, 1984. This January 14, 1985, response was received on January 15, 1985, and is under review.

INTERSTATE DOCUMENTATION

All of the samples submitted with this recommendation were collected at Cordis Corporation. All samples are accompanied by an invoice which shows the pacers were shipped to consignees outside the State of Florida, with the exception of DOC 84-268-851, which was shipped to Dr. , Miami, Florida. Records of interstate movement were not available at the Cordis Corporation. Reportedly pacers are shipped by either U.S. Postal Service, Federal Express, or United Parcel Service.

We will document the interstate nature of the shipments by visiting the consignees and obtaining records and affidavits from them. If this fails to adequately document the samples, we will document the interstate movement of pacer components.

EXHIBITS

Attached to this memorandum as exhibits are the following:

Exhibit 1 is a list of the establishment inspections conducted at the Cordis Corporation between December 3, 1983, and November 15, 1984. Copies of all of the establishment inspection reports with exhibits have been submitted to CDRH (HFZ-320) and will not be resubmitted with this recommendation.

Exhibit 2 is a list of currently ongoing recalls by Cordis.

SAMPLES

Attached are the following sample collection reports on which this recommendation is based:

DOC 84-268-851, Model 337A Multicor Gamma pacer, documents a "charity" pacer.

DOC 84-268-852, Model 233F Sequicor II pacer, documents a heat-stressed pacer shipped with the original batteries after corrections were made in production.

DOC 84-374-482, Model 334A Omni-Stanicor Gamma pacer, documents a pacer with polypropylene protected feedthrough shipped after feedthroughs were protected with polyimide.

DOC 84-374-484, Model 334A Omni-Stanicor Gamma pacer, documents a pacer with unprotected feedthrough shipped after feedthroughs were protected by polypropylene.

DOC 84-374-485, Model 340A Multicor Gamma pacer, documents a so-called "pediatric" pacer which was distributed without submission of 510(k) notification.

DOC 84-374-546, Model 190A Omni-Stanicor Lambda pacer, documents a pacer with a printed wiring board with unfilled plated through holes. This pacer was shipped after the decision was made to fill the holes with solder.

DOC 84-374-547, Model 221B7 Stanicor Theta pacer, documents a pacer with a failed printed wiring board.

DOC 85-374-555, Model 233F Sequicor II, documents a heat-stressed pacer.

DOC 85-374-556, Model 333D7 Stanicor Gamma, documents a heat stressed pacer and a pacer with an extended UBD.

SUMMARY

In 1975, Cordis Corporation was warned that their operation required strengthening in several broad areas in order to assure that pacemakers which were not adulterated or misbranded were being marketed. Inspections from 1975 through December 1983 demonstrated compliance with the CGMP regulations for medical devices. Deficiencies were found but they did not appear to be more than isolated instances and did not represent significant GMP problems.

Since December 3, 1983, 15 inspections have been made at the Cordis Corporation. These inspections show that adulterated and misbranded pacemakers have been distributed by the firm. Inspection has shown that pacers (Gamma and Theta) have failed after being exposed to temperatures of 115° C for extended periods of time (batteries in these pacers should not be exposed to heat in excess of 54.5° C); pacers (Lambda and Theta) have failed due to failure of the printed wiring boards, causing a sudden no-output failure, and hundreds of Gamma pacers have failed due to early battery depletion. Also, pacers have been changed significantly and have been marketed without submission of 510(k) premarket notification, supplemental 510(k), or supplemental PMA's.

Since December 1983, the firm has inititated five (5) recalls, notifications, or safety alerts involving more than 14,000 pacemakers, 5,025 catheters, and 935 catheter sheaths. FDA inspected the catheter production operation between April 4 and 27, 1984, and no significant problems were observed.

Orlando District believes that all of the above demonstrate violations of the Federal Food, Drug, and Cosmetic Act for which the firm should be prosecuted. However, our inspections have failed to elicit evidence that the officers of the corporation had *direct* responsibility and knowledge of these violations. There is no evidence that the individual(s) responsible for the operation of this firm had direct prior knowledge of the distribution of violative pacemakers. However, management has the responsibility to control operations, assure quality, evaluate problems and complaints, and conform to good manufacturing practices. Unless the agency is willing to proceed with a prosecution of responsible individuals by relying on the Park decision, we believe that a Grand Jury is the best forum for obtaining evidence of their responsibility.

The Grand Jury should determine whether the violations found were unintentional on the part of management or whether the violations were the result of deliberate, intentional acts to violate the law.

We believe the agency should take advantage of the offer of Cordis' former employee, , to review the 510(k) notifications, premarket approval applications, supplements, and investigational device exemptions which prepared while an employee of Cordis. can then testify before the Grand Jury concerning areas in those documents which contain false information, manipulated data, and data which was intentionally omitted. Title 18 charges may result if the Grand Jury obtains evidence to corroborate the allegations.

John J. Miceli
Compliance Officer
Orlando District

Edward R. Atkins
Director, Compliance Branch
Orlando District

Adam J. Trujillo
District Director
Orlando District

cc:
GCF-1/Levine
HFC-200/Shumate
HFC-320/Damaske
HFR-41/Kinslow
HFR-4575

bcc:
HFR-4200/AJT/EI File
HFR-4240/JJM
HFR-4250/CCR.
Draft:JJM/dar/1-7-85
Redrafted:JJM/dar/1-11-85
DEC'd to HFR-4575/Casey 1-11-85
Redrafted:JJM/dar/1-28-85
Redrafted:JJM/dar/2-1-85
Redrafted:JJM/dar/2-11-85
Redrafted:JJM/dar/2-15-84
Redrafted:JJM/dar/2-20-85
Final:AJT/ERA/JJM/dar/2-21-85

JJM001/2

EXHIBIT 1

LIST OF EIR'S OF CORDIS CORP. WITH MAIN TOPICS

December 3-22, 1983 - EBD in Gamma pacers; battery manufacturing operation.

January 17-April 2, 1984 - Continuation of previous inspection; evaluation of polypropylene and polyimide coating of glass feedthrough insulators in Gamma cells; alteration of August 19, 1983, task force memo.

March 15-April 6, 1984 - Polyurethane leads.

April 4-27, 1984 - Recalled angiographic catheters.

April 4-May 18, 1984 - EBD in Gamma Pacers; 200 Gamma cell study; Model 340A Mini-Gamma Pacer.

April 16-May 15, 1984 - Polyurethane leads; balloon-tipped catheters; complaint handling system; PET's.

April 16-June 26, 1984 - Investigation of second anonymous complaint. Handling of complaints by the legal department; crosstalk in Gemini Model 415A pacer.

May 22-June 5, 1984 - Printed wiring board, reed switch, and EBD failures.

May 31-June 20, 1984 - Model 255 and 256 programmers; Models 233 and 415A pacers.

June 20 - August 10, 1984 - IDE G840004, Orthocor Antitachycardia Pacer.

July 23-August 16, 1984 - Charity pacers; complaint handling by the legal department; heat-stressed pacers.

August 31-October 12, 1984 - Cross-talk; IDE Model 415A Pacer.

September 14-October 10, 1984 - Heat-stressed pacers; Model 261 pacer kit.

October 3-5, 1984 - Accountability of charity pacers.

October 12-November 15, 1984 - CGMP inspection.

EXHIBIT 2

Recalls - Product Notifications - Safety Alerts

Z-064-4) Z-065-4) Z-066-4) Z-067-4)	Gamma series pacers (333B7, 334A, 336A, 336B, 337A, and 340A) containing lithium batteries manufactured in 1979 through October 1980. Because of early battery depletion due to self-discharge.
Z-146-4) Z-147-4)	Ducor Angiographic Catheter because of leakage at the hub.
Z-059-5) Z-060-5)	Gamma and Theta series pacers because the pacers were heat-stressed to 115° C.
M-001-5)	Gemini Model 415A series pacers because of crosstalk.
Z-113-5)	5-French Catheter Sheath because the lumen is not large enough to permit entry of the 0.032 inch guidewire supplied with the catheter.

4th Anonymous Complaint"

cordis.©
Cordis Corporation
Post Office Box 370428
Miami, Florida 33137, U.S.A.
Telephone 305 578-2000

The Director
Food And Drug Administration
Washington D.C.

Feb 25,1985.

SUB : Unsafe Products Manufectured By CORDIS CORP.

Dear SIr,

The battery used in Pacemaker is not safe.We have lots of problems of leak. They recently used some battery rejected for above reason. I am in taskforce for documentation for battery. This looks to me a coverup to show the F D A that we are doing something as recommended by your Inspectors. Some of the pacemakers do not function per their claims. Some times orders come from top management to use some quistionable batteries rejected by quality control. As per my opinion they are playing with human life. FDA should investigate this area thoroughly. This should be treated as confidential otherwise I loose my job.

Sincerely Yours

C.K
C.K.

C.C. Consumer Association.(Pacemaker)

85-03-1-1

Att 2-32c
(T. Moore)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administrati
8757 Georgia Avenue
Silver Spring MD 20910

FEB 28 1985

Norman R. Weldon, Ph.D., President
Cordis Corporation
10555 West Flagler Street
Miami, Florida 53172

Dear Dr. Weldon:

We have reviewed the draft "Dear Doctor" letter that Mr.Richard Morey sent to us on January 25, 1985, regarding Lamda and Theta series pacers.

We note that over an approximate eight week period there have been 28 reports of explants of Lamda and Theta series pacers due to sudden no output or intermittent output reported to us under the Medical Device Reporting rule. Because of the significant number of explants reported as a result of the potential for sudden no output we do not believe your proposed communication can be considered a safety alert as recommended by Mr. Morey. We consider this communication to be a recall and the letter and envelope should be flagged "Important : Pacer Recall."

We believe it is important ~~the~~ the problem be stated in the first paragraph whenever physicians are being alerted of significant health hazards. Further, the listing of the data for "Printed Wiring Board Failures" and "Feasibility" data on page two of your draft detracts from the significance of the notification. Therefore, we recommend that the data on page two be ommitted.

We are concerned that your draft letter only covers four models of pacers (190A, 190E, 221A7, and 221B7). The printed wiring boards with open plated through holes used in combination with the crimped D cell batteries are present in nine additional models (188B7, 208A, 215, 235A, 235B, 236A7, 236B7, 238B7 and 241R). Similar failures (approximately eleven) have occured in at least five of these additional models (188B7, 208A, 215A, 235A, and 235B) and we have no reason to believe that similar failures will not occur in the remaining four models. Therefore, we recommend that these nine additional Lambda and Theta models be included by a recommendation of monthly mointoring.

We have suggested changes and deletions in the enclosed draft and recommend that all physicians and hospitals to whom these pacemakers have been distributed be immediately notified of this serious potential problem. Further, any pacemakers not implanted, including those on consignment, should be recalled.

One remaining question we have concerns the details of your Cordis Patient Protection Agreement. Please tell us what this program includes. Does it pay for monitoring and medical replacement costs, etc?

Sincerely yours,

Walter E. Gundaker, Director
Office of Compliance
Center for Devices
and Radiological Health

cc: Mr. Harold Hershenson, Executive
Vice President
Cordis Corporation
P.O. Box 525700
Miami, Florida 33152

Richard S. Morey
Kleinfeld, Kaplan and Becker
1140 19th Street, N.W.
Washington, DC 20036

IMPORTANT: PACER RECALL

POTENTIAL SUDDEN LOSS OF OUTPUT ON LAMBDA SERIES PACER MODELS
190A, 190E, 188B7, 208, 215, 235A, 235B, 236A7, 236B7, 238B7,
AND IN THETA SERIES PACER MODEL 221A7, 241A, AND SERIAL
NUMBERS BELOW 12,000 of THETA SERIES MODEL 221B7

Dear Doctor:

Cordis is distributing this information to specifically inform all physicians who are monitoring patients with the above model pacers of the possibility of sudden no output failures. These failures may also be characterized by intermittent output, rate decrease, intermittent pacing and sensing and loss of capture and sensing; therefore, monthy monitoring is essential. Furthermore, since the loss of output has occured suddenly in a significant number of units, Cordis recommends consideration of prophylactic replacement of 190A, 190E, 221A7 and serial numbers below 12,000 of Model 221B7 pacer-dependent patients.

The sudden loss of output in these listed models has been determined to be caused by failure of the "plated-through holes" which connect the two sides of the printed wiring board. Other models of Cordis pacers are not susceptible to this failure mechanism because their designs do not include plated-through holes or because the plated-through holes are filled with solder to prevent failure of the plated conductor.

The normal Cordis Patient Protection Agreement will apply to any unit removed prophylactically even if it is found to be functioning within specifications when returned to Cordis. If you have any questions regarding this notification please call James Fortino in Cordis Customer Service, toll free, at 1-800-327-2490, Ext. 2019. Within Florida, please dial 1-800-432-6565.

VINCENT A. KLEINFELD
ALAN H. KAPLAN
ROBERT H. BECKER
THOMAS O. HENTELEFF
RICHARD S. MOREY
PETER O. SAFIR
NANCY SINGER
KINSEY S. REAGAN
PETER R. MATHERS
DAVID E. KAPLAN

LAW OFFICES
KLEINFELD, KAPLAN AND BECKER
1140 NINETEENTH STREET, N. W.
WASHINGTON, D. C. 20036

TELEPHONE
(202) 223-5120

TELECOPIER
(202) 223-5619

March 7, 1985

Mr. William H. Damaska (HFK-110)
Food and Drug Administration
8757 Georgia Avenue
Room 1248
Silver Spring, MD 20910

Dear Mr. Damaska:

Following up on our commitment at yesterday's meeting, I enclose a revised version of the notification on Lambda and Theta series pacers.

As indicated during the meeting, Cordis is very concerned as to how FDA intends to classify this notification for inclusion on its enforcement report. It is Cordis' position that classifying this notification as Class I would be unreasonable and inappropriate in view of the prior notifications of the problem to the medical profession through Cordis Product Updates and due to the relatively low and steady level of reported defects.

We particularly note that, since FDA reportedly determines classification based on the situation before issuance of the notification, the prior notices to the medical profession and the evidence (sample PSR's) submitted at the meeting that physicians are aware of and acting upon these prior notices should be taken into account in determining the appropriate classification. Under the circumstances, we submit that this should be classified no higher than a Class II recall.

As indicated at the meeting, Cordis will also prepare a health hazard evaluation concerning this notification and submit it for agency consideration as soon as possible.

If you have any questions about this matter, please let me know.

Yours very truly,

Richard S. Morey

Richard S. Morey
Counsel for Cordis

RSM/jlr

Enclosure

cc: Mr. Hershenson

OK Ltr
HFZ-?D
3/8/85

[illegible] That [illegible] other
models not tested but
with pacemaker should be [illegible]
[illegible] not treated
[illegible] 3/8/85

x 025700
mi, FL 33102-5700, U.S.A.
elephone 305-551-2000
Telex 6811112

Cordis.

IMPORTANT MEDICAL DEVICE NOTIFICATION

POTENTIAL SUDDEN LOSS OF OUTPUT IN

LAMBDA SERIES PACER MODELS 190A and 190E

THETA SERIES PACER MODEL 221A7 and

THETA SERIES PACER MODEL 221B7 WITH SERIAL NUMBERS BELOW 12,000

Dear Doctor:

Cordis is distributing this notification to inform all physicians who are monitoring patients with the above models about the possibility of sudden no output failures in a small, but significant, number of these pacers (see addendum). The sudden loss of output in the listed models has been determined to be caused by failure of unfilled "plated through-holes" which connect the two sides of the printed wiring board.

Cordis recommends prophylactic replacement of Model 190A, 190E, 221A7 and Serial Numbers below 12,000 of Model 221B7 pacers in pacer-dependent patients.

Cordis first reported a low level of no output failures in Model 190A and 190E pacers in the April, 1982, issue of its semi-annual Product Update which is sent to about 15,000 physicians and the Food and Drug Administration. The occurrence of similar no output failures in Models 221A7 and 221B7 was first reported in the April, 1983, Product Update. Cordis, in the October, 1984, Product Update recommended consideration of prophylactic replacement of these models in pacer-dependent patients.

The Cordis Patient Protection Agreement will apply to any unit of the above models removed prophylactically, even if it is found to be functioning within specification, when returned to Cordis. Cordis regrets any inconvenience this notification may cause you or your patients. If you have any questions regarding this notification, please call Cordis Customer Service, toll free, at 1:800:327-8085 (or 1:800:432-6565 in Florida.)

Attach.

ADDENDUM

Model.	Printed Wiring Board Failures		Reliability, All Failures		
	% per implant month	% of implants to date	Predicted *	Achieved **	At Month
190A	0.050	3.53	0.898	0.898	105
190E	0.065	4.24	0.918	0.900	89
221A7	0.043	2.48	0.966	0.962	75
221B7***	0.018	0.82	0.969	0.972	68

* Based on prediction at time of introduction, adjusted for time.

** Calculated by the cumulative survival method from Cordis Pacer Registry as of February 1, 1985.

*** Serial numbers less than 12,000.

File

Prep:JHSamalik:3/8/85; Initial:LJStauffer:3/8/85; WHDamaska:3/8/85
R/D:RRobinson:3/8/85; Initial:RASkufca:3/11/85; ABHolt:3/12/85
WEGundaker:3/13/85; F/C:RRobinson:3/15/85
cc: HFZ-300 HFZ-320 HFZ-321 HFC-20 (M. Schumate) HFC-162 HFR-41
HFR-4200 HFR-4575

Mr. Richard S. Morey
Kleinfield, Kaplan and Becker
1140 Nineteenth Street, N.W.
Washington, D.C. 20036

Dear Mr. Morey:

This is in reply to your letter of March 7, concerning Cordis' revised letter on the Lambda and Theta series pacers, and the classification of this action.

Based on the data submitted on these pacers at our March 6, meeting, it is our opinion that the Lambda Series Models 188B7, 208A, 215A, 235A and 235B should be included in the proposed letter with a recommendation that pacer dependent patients be closely monitored. (Please see enclosed draft for suggested changes). We realize that the number of failures for these models are substantially less than the failures for models which are being recommended for prophylactic replacement. However, we believe that the potential for failure has been demonstrated.

As to the classification of this action, we plan to classify it as a Class I recall. As was stated in our meeting, all actions involving recalls are evaluated based on situations before the issuance of any type of notification. Therefore, we disagree with your argument that prior notices reduce the potential health hazard of sudden no output failure. The notices may have made the medical profession aware of the problem, but did not have the impact of a recall letter.

Sincerely yours,
/s/
Ann B. Holt

Walter E. Gundaker, Director
Office of Compliance
Center for Devices and
Radiological Health

Enclosure

cc: Norman R. Weldon, Ph.D., President
Cordis Corporation
10555 West Flagler Street
Miami Florida 53172

Mr. Harold Hershenson, Executive
Vice President
Cordis Corporation
P.O. Box 525700
Miami, Florida 33152

phone 305-551-2000
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IMPORTANT MEDICAL DEVICE [redacted] RECALL

OTENTIAL SUDDEN LOSS OF OUTPUT IN

LAMBDA SERIES PACER MODELS 190A and 190E, 188B7, 208A, 215A, 235A and 235B

THETA SERIES PACER MODEL 221A7 and

THETA SERIES PACER MODEL 221B7 WITH SERIAL NUMBERS
BELOW 12,000

Dear Doctor:

Cordis is distributing this notification to inform all physicians who are monitoring patients with the above models about the possibility of sudden no output failures in a small, but significant, number of these pacers. ([redacted]) The sudden loss of output in the listed models has been determined to be caused by failure of unfilled "plated through-holes" which connect the two sides of the printed wiring board.

Cordis recommends prophylactic replacement of Model 190A, 190E, 221A7 and Serial Numbers below 12,000 of Model 221B7 pacers in pacer-dependent patients.

Cordis first reported a low level of no output failures in Model 190A and 190E pacers in the April, 1982, issue of its semi-annual Product Update which is sent to about 13,000 physicians and the Food and Drug Administration. The occurrence of similar no output failures in Models 221A7 and 221B7 was first reported in the April, 1983, Product Update. Cordis, in the October, 1984, Product Update recommended consideration of prophylactic replacement of these models in pacer-dependent patients.

The Cordis Patient Protection Agreement will apply to any unit of the above models removed prophylactically, even if it is found to be functioning within specification, when returned to Cordis. Cordis regrets any inconvenience this notification may cause you or your patients. If you have any questions regarding this notification, please call Cordis Customer Service, toll free, at 1:800:327-8085 (or 1:800:432-6365 in Florida.)

CORDIS ALSO RECOMMENDS THAT PACER DEPENDENT PATIENTS WITH MODEL 188B7, 208A, 215A, 235A AND 235B PACERS BE CLOSELY MONITORED. THE FAILURE RATE WITH THESE MODELS IS SIGNIFICANTLY LESS THAN THE MODELS DISCUSSED ABOVE.

[redacted]

Len / John S.

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We will need to respond to this until you prepare
WHD
3/15/85

March 15, 1985

Note: I kept a copy.

Mr. William H. Damaska
(HFK-110) Room 1248
Food and Drug Administration
8757 Georgia Avenue
Silver Spring, MD 20910

Dear Mr. Damaska:

As promised in my letter of March 7, 1985, Cordis has prepared a health hazard evaluation concerning the notification on Lamda and Theta Series pacers. Two copies are enclosed for your review and for FDA's use in determining the classification of this notification.

If you have any questions about this, please let me know.

Yours very truly,

Richard S. Morey

Enclosure

RSM:emw

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Cardiovascular Instrumentation

cordis

Health Hazard Evaluation

Date: March 12, 1985

1. Product: Certain units of Lambda Series pacers (Models 190A and 190E) and Theta Series pacers (Models 221A7 and 221B7 through Serial Number 12,000).

2. Manufacturer: Cordis Corporation, Miami, Florida.

3. Product Description and Usage: All affected models are single channel, ventricular pacers intended for use in patients who have bradycardia due to sinus node dysfunction or heart block.

   Model 190A is a programmable, unipolar pacer. Rate is programmable from 60-100 ppm and output current is programmable from 2-9 mA. Modes are programmable to VVI (R-wave inhibited) or VOO (asynchronous).

   Model 190E is identical to 190A except that its rate is programmable from 50-120 ppm.

   Models 221A7 and 221B7 are nonprogrammable, unipolar VVI (R-wave inhibited) pacers with a fixed rate of 70 ppm and a nominal output current of 6.5 mA.

4. Reported Problem, Incident, Defect, Deficiency, Malfunction or Failure: Sudden or intermittent loss of output due to failure of unfilled "plated-through holes" which connect the two sides of the printed wiring board. While these units are typically meeting reliability predictions made at the time of their introduction and adjusted for time, there have been a small, but significant, number of no-output failures because of this discrepancy.

5. Number of Adverse Effects, Disease, Injuries, or Deaths that have Occurred from Use of the Product: Cordis is not aware of a death directly associated with this failure mode. During the past three years, there have been a few (approximately 12) reports citing syncope, fatigue, dizziness, and faintness experienced by the patients. In each instance, the pacer was replaced successfully and the patient's condition relieved.

   We would consider these incidents as a temporary condition that was alleviated without significant consequence even though these particular incidents reportedly involved some pacer-dependent patients. There have been two other reports involving either asystole or cardiac arrest, requiring resuscitative measures by the physician. In both instances, the pacers were replaced and the patients recovered. Clearly these two incidents were more serious than the others but, considering that there are 27,125 registered implants of these Lambda and Theta units, the incidence of reported "injuries" is extremely low. By far, the great majority of reported events involve no "injury" and uneventful replacement of the pacer.

6. Technical Evaluation: This failure mode has not occurred in other Lambda or Theta models except in isolated instances. The potential for this failure mode has been eliminated in other models by design changes or by filling (soldering) the plated-through holes.

7. Medical Evaluation: The potential hazard to the patient whose pacer develops an intermittent or sudden loss of output is bradycardia or asystole as determined by the patient's underlying rhythm. In units in which the unfilled plated-through holes do not present a problem, a normal rate decrease with battery depletion (two or more beats per minute) can be expected to occur and this can be detected by normal pacer monitoring procedures.

8. Identified Hazard or Risk Resulting from the Use or Exposure to the Product: The probability of serious adverse health consequences from the use of these pacers is remote, except in the rare case in which the patient's underlying rhythm is so inadequate that syncope or cardiac arrest occurs (two such incidents reported to date in 27,125 registered implants, many of which took place over seven years ago).

9. Clinical Consequences that May Result from the Hazard: Obviously, an intermittent or sudden loss of pacer output in a very pacer-dependent patient could result in adverse health consequences or death. In my experience, however, the chances of this happening are extremely remote. In fact, in an analysis of 191 unpredicted pacer failures over a four-year period, there were no known deaths between the time the pacer failure was identified and successful replacement had taken place (see reference).

10. Conditions or Factors which May Contribute to or Reduce the Hazard or Risk: In the unusual instance that a patient has demonstrated complete pacer dependency (at the time of surgery or postoperatively by pacer programming and/or overdrive suppression), prophylactic pacer replacement should be performed. This action should also be considered if normal pacer followup is impossible or impractical (uncooperative patient, lack of monitoring capabilities, etc.). In all other instances, it is in the best interest of the patient to monitor pacer function at regular intervals, either by office visits or telephone monitoring. Because most of the involved pacers have been in place for several years, it is safe to assume that many patients are already under intensified monitoring schedules purely on the basis of elapsed time since implant.

    As an additional precaution, Cordis has published a series of Product Updates which have been sent to approximately 15,000 physicians listed in the Cordis pacer registration database and to the FDA. The plated-through hole discrepancy in Lambda Models 190A and 190E was described in the Cordis Product Update of April, 1982 and in subsequent Updates. The same discrepancy in Theta Models 221A7 and 221B7 was described in the April, 1983 Product Update and in subsequent Updates, the most recent being issued in October, 1984. The Product Updates recommend that the physician consider prophylactic replacement of affected units in pacer-dependent patients. Confirmation that physicians have received, read and acted on the recommendations made in the Product Updates is reflected by comments written in Out-Of-Service Reports which accompany explanted units which are returned to Cordis.

11. Probability of Adverse Health Consequences Resulting from Use or Exposure to the Product: I feel confident that this is a situation in which only a small number of patients will experience temporary or medically reversible adverse health consequences (approximately 18% of the patients who experience unpredicted pacer failure). Only 6% of patients will have sufficient symptomatology to require a temporary pacing system and, even in such cases, the probability of serious adverse health consequences is extremely remote.

12. Summary: Provided that prophylactic pacer replacement is performed in very pacer-dependent patients, any medical risk resulting from intermittent or sudden loss of pacer output in the Lambda and Theta pacers described herein is reversible and temporary, and the probability of serious health consequences is remote. The Agency can be assured that Cordis will continue to follow the effectiveness of its Product Updates and will ensure that every effort will be made to keep physicians managing patients with affected pacers informed about the problem and its recommended management.

CORDIS CORPORATION

D. C. McGregor

David C. MacGregor, M.D., F.R.C.S.(C), F.A.C.S., F.A.C.C.
Vice President

DCM/nf

Reference: MacGregor, D.C., Noble, E.J., Morrow, J.D., Scully, H.E., Covvey, H.D., and Goldman, B.S.: Management of a Pacemaker Recall, Journal of Thoracic and Cardiovascular Surgery 74:657-667, 1977.

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March 26, 1985

Mr. William Damaska
(HFK-110) Room 1248
Food and Drug Administration
8757 Georgia Avenue
Silver Spring, MD 20910

Dear Mr. Damaska:

This will respond to Mr. Gundaker's letter of March 15, 1985 concerning the notification on Lambda and Theta series pacers and the classification of this notification.

Cordis disagrees very strongly with the Class I recall classification announced for this notification in the March 15, 1985 letter. It notes that this classification was made without consideration by the agency of Cordis' health hazard evaluation of this notification which was sent to the agency on March 15, 1985, the same day on which Mr. Gundaker's letter was issued. A copy of the Cordis health hazard evaluation and our earlier letter transmitting it are enclosed again for your information. In order to try and resolve the classification issue, Cordis intends to request a meeting at an appropriate higher level within the agency to consider this issue further. I will be in touch with you at the end of this week to discuss such a meeting.

Cordis also has reviewed and further revised the draft notification enclosed with Mr. Gundaker's letter. A new draft is enclosed for the agency's consideration. The main change made was to eliminate entirely from the notification Models 235A & 235B for which there had been no printed wiring board failures after 66 months of service in field returns and only one such failure among 17 pacers on life test. It is Cordis' position that the possibility of failures for these models is too remote to justify recommending even increased periodic monitoring. Another change was to move Model 221B7 (serial numbers below 12,000) from the prophylactic replacement category to the monitoring category. An examination of the percentage failure per implant months column on the addendum to the new draft notification shows a failure rate which is significantly lower than the others for which prophylactic replacement is recommended and consistent with the failure rates for the other models for which monthly monitoring is recommended. Cordis has also included the addendum with the notification because it believes that providing precise information of this type is essential to the monitoring physician. Finally, Cordis has titled the communication as "notification" rather than a "recall" in line with a long-standing agreement with the Bureau of Medical Devices that "recall" is not an appropriate term for warnings about implanted cardiac pacers.

Please let us have the agency's comments on the revised draft as soon as possible. If you have any questions, please call me or Harold Hershenson at Cordis.

Yours very truly,

Richard S. Morey
Counsel for Cordis Corporation

RSM/jlr

Enclosures

March 23, 1985 DRAFT

IMPORTANT MEDICAL DEVICE NOTIFICATION

POTENTIAL SUDDEN LOSS OF OUTPUT IN
LAMBDA SERIES PACER MODELS
188B7, 190A, 190E, 208A, AND 213A
AND
Non-Programmable THETA SERIES PACER MODELS
221A7 AND SERIAL NUMBERS BELOW 12,000 OF MODEL 221B7

Dear Doctor:

Cordis is distributing this notification to inform all physicians who are monitoring patients with the above models about the possibility of sudden no output failures in a small, but significant, number of these pacers (see addendum). These failures have been determined to be caused by the breaking of unfilled "plated through-holes" which connect the two sides of the printed wiring board after 30 or more months of implant for the Lambda Series and 18 or more months for the Non Programmable Theta Series.

Cordis recommends prophylactic replacement of Model 190A, 190E and 221A7 pacers in pacer-dependant patients. Sudden no output failures have occurred at a lower rate in Models 188B7, 208A, 213A and in Serial Numbers below 12,000 of Model 221B7. Cordis recommends that pacer-dependant patients with these model pacers be monitored monthly.

Cordis first reported a low level of no output failures in Model 190A and 190E pacers in the April, 1982, issue of its semi-annual Product Update which is sent to about 15,000 physicians and the Food and Drug Administration. The occurrence of similar no output failures in Models 221A7 and 221B7 was first reported in the April, 1983, Product Update. Cordis, in the October, 1984, Product Update recommended consideration of prophylactic replacement of these models in pacer-dependent patients.

Either option A of the Cordis Patient Protection Agreement or a prorated credit may be selected to apply to any unit of the above models removed prophylactically and replaced with a Cordis pacer, even if the replaced pacer is found to be functioning within specification when returned to Cordis. Cordis regrets any inconvenience this notification may cause you or your patients. If you have any questions regarding this notification, please call Cordis Customer Service, toll free, at 1-800-327-8085 (or 1-800-432-6363 in Florida).

Attach.

ADDENDUM

MODELS FOR WHICH PROPHYLACTIC REPLACEMENT IS RECOMMENDED IN PACER DEPENDENT PATIENTS

	Printed Wiring Board Failures		Reliability*, All Failures	
	%/Implant Month	% To Date	Achieved	At Month
190A	0.050	3.60	0.897	106
190E	0.067	4.46	0.865	90
221A7	0.044	2.62	0.958	76

MODELS FOR WHICH MONTHLY MONITORING IS RECOMMENDED IN PACER DEPENDENT PATIENTS

	Printed Wiring Board Failures		Reliability*, All Failures	
	%/Implant Month	% To Date	Achieved	At Month
188B7	0.011	0.53	0.979	65
208A	0.015	0.74	0.957	75
215A	0.017	0.83	0.989	63
221B7**	0.018	0.82	0.972	69

* Calculated by the cumulative survival method from Cordis Pacer Registry as of March 1, 1985.

** Serial numbers less than 12,000.

APR 4

Mr. Richard S. Morey
Kleinfeld, Kaplan and Becker
1140 Nineteenth Street N.W.
Washington, D.C. 20036

Dear Mr. Morey:

This is to acknowledge receipt of your March 15 letter, addressed to Mr. Damaska, containing two copies of Cordis' Health Hazard Evaluation on the Lambda and Theta Series Pacers.

This data will be considered in our review and evaluation.

Sincerely yours,

John H. Samalik
Recall and Notification Branch
Center for Devices
  and Radiological Health

Prep:JHSamalik:3/29/85; Initial:WHDamaska:4/3/85; R/D:RRobinson:3/29/85; F/C:RRobinson:4/4/85

cc: HFZ-300 HFZ-320 HFZ-321/3 HFA-224

File

4/1/85
S.T

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Cardiovascular Instrumentation

cordis.

Cordis Memo
4/22/85 S.T
attach 1, p 1 of 6

PRELIMINARY

LAMBDA AND THETA SERIES PACERS

NOTIFICATION DISTRIBUTION LIST

Total No. of pacers involved in the notification 28,931

Monitoring Physicians/Pacers . . .

United States	4813 -	17,489 pacers
Canada	167 -	1,427 "
Far East	207 -	479 "
Latin America	408 -	1,243 "
Cordis Europa	254 -	939 "
TOTAL	5849	21,577 pacers

Hospitals/Distributors . . .

United States	384 -	783 pacers
Canada	2 -	35 "
Far East	20 -	531 "
Latin America	23 -	297 "
Cordis Europa	3 -	5,593 "
TOTAL	432	7,239 pacers

Total No. of pacers distributed to Cordis Sales (Miami)

16 accounts - 20 pacers

Total No. of pacers distributed to Cordis Misc. (Miami)

3 accounts - 95 pacers

Total No. of V.A. hospitals involved - 44 (included in totals above)

:mda
4/19/85

Volume 1

cordis

CORDIS RESPONSE TO FD 483'S
OF APRIL 2/84 AND MAY 15/84

Cordis Corporation
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Cardiovascular Instrumentation

cordis.

May 31, 1984

Mr. Carl C. Reynolds
Acting District Director
Food and Drug Administration
7200 Lake Ellenor Drive, Suite 120
Orlando, FL 32809

Dear Mr. Reynolds:

Accompanying this letter are Cordis point-by-point responses to the FD 483 Inspectional Observations presented to Cordis on April 2 and May 15, 1984, on inspections relative to Cordis Gamma Series cardiac pacers.

Cordis has studied the FD 483 reports and the background surrounding the observations in them very carefully. Its responses not only address the observations directly but attempt to address FDA concerns reflected in the observations. Cordis has included a copy of the observations with its response and has included as exhibits copies of documents referenced in the responses, to facilitate review by the FDA. Further, duplicate copies of the FDA observations and Cordis responses have been marked to indicate trade secret and other proprietary information which Cordis requests not be released in response to Freedom of Information inquiries. Cordis considers all of the exhibits to the responses except Exhibits 35-1, 43-3, and 110-1 to be nondisclosable proprietary information.

Cordis has always strived and will continue to strive to comply fully with all FDA requirements and to maintain a good working relationship with the FDA. However, these inspections relating to Gamma pacers spanned more than six months and seemed to start on a suspicious note. This is probably due to anonymous allegations and Cordis documents concerning the Gamma pacer which apparently were provided to the FDA through an extensive industrial espionage activity. Cordis realizes that the FDA is obligated to investigate all allegations and information, regardless of their source, to determine whether there have been any violations of the law. Cordis has cooperated completely with the FDA investigations and will continue to do so. Cordis is confident that no serious violations have occurred.

To help to place the observations and responses relating to the Gamma series Notification and Cordis activities leading to the Notification in historical perspective, Cordis is providing additional background information in this letter about the events which led to the December 5, 1983, Notification.

In addition, after reviewing the observations, Cordis has recognized the need for improvements in some of its policies and procedures. This letter describes significant revisions being made in Cordis policies and procedures as a result of the inspectional observations.

Cordis also notes that many of the observations relate to instances in which individual employees failed to follow Cordis policies and procedures. Cordis is addressing these failures by making its policies and procedures more explicit and by retraining and improving the training of the responsible employees.

A. HISTORICAL PERSPECTIVE

The FDA Investigators have tried to determine whether Cordis was diligent and prudent in the qualification of the hermetic Gamma cell and in responding promptly to the problem of early depletions of Gamma cells. Their review was made, of course, after the cause of the problem was established by Cordis. With the clarity of hindsight, the relevance of certain data or events to the cause of the problem now seems readily apparent. However, it must be borne in mind that these events and data were not so obviously relevant before the cause of the problem was determined, and especially before it was realized that there was a problem at all. The following review is intended to place these events and data in the context of what was known when they occurred and the effect of this limited knowledge on Cordis decisions.

1. The Failure Mechanism

Although Cordis still has no direct evidence that it occurs in field failures of Gamma cells, the failure mechanism appears to start with the electrodeposition of lithium metal on the glass feedthrough insulator. This is an unexpected phenomenon from an electrochemical standpoint because the voltage necessary to reduce lithium ion to lithium metal is higher than any voltage generated in a Gamma cell. However, this deposition appears to occur through a hypothetical mechanism of "underpotential electrodeposition". Lithium metal is conductive and, if the deposit spans the glass insulator, it can provide a path for self-discharge of the cell. The reaction of water with corroded glass insulators with the release of hydrogen gas indicates the presence of lithium. However, the measured resistance of feedthroughs with corroded glass has not been sufficiently reduced to confirm this failure mechanism except in a few cells stored at very high temperatures.

Cordis has hypothesized (see the 510(k) submitted to FDA on April 4, 1984) that the lithium metal deposits on the glass, forming a conductive path and causing self-discharge of the cell. The lithium then reacts with the glass, causing corrosion and forming a non-conductive lithium compound. Thus, low resistance will be detected only if the resistance is measured before the lithium disappears by reacting with the glass. The transient nature of the conductive pathway prevents confirmation of the failure mechanism by resistance measurement and led Cordis for many months to consider alternative theories as to how self-discharge occurred.

2. Development of the Gamma Cell

The lithium-cupric sulfide cell was developed by the DuPont Company in the early 1970's to provide a cell which could be stored in tropic heat or arctic cold for extended periods of time without self-discharge. Cordis has manufactured cells for cardiac pacers under license from DuPont since 1975. The original DuPont and Cordis cells were non-hermetic, crimped cells. They have been used to power the Cordis Lambda and Theta series of pacers. Except for some early depletions of the initial Lambda cells, which were eliminated by immediate "burn-in" of the cells after assembly, the Cordis lithium cupric sulfide cell has demonstrated the best long-term reliability of any pacer power source except the nuclear battery. This high reliability in many thousand Cordis pacers has been documented by the Bilitch reports on pacer performance published bimonthly in the PACE Journal.

The Gamma cell was developed to provide a more compact, hermetically-sealed power source for the new, smaller Gamma series of pacers using the established lithium cupric sulfide system. The hermetic design required the addition of a feedthrough and other mechanical modifications, but the cell chemistry, which had proved to be very reliable, was unchanged. The Gamma pacer was first marketed in 1979 after qualification of the Gamma cell and Gamma pacer and after approval of a 510(k) Notification by FDA.

3. Discovery of Glass Corrosion

Feedthrough glass corrosion in the hermetic lithium cupric sulfide cell was first discovered by Chemist Stan Solomon of Cordis in early August, 1980. Up to that time, there had been no self-discharge in any DuPont crimped lithium cupric sulfide cells after nine years, or in any Cordis crimped lithium cupric sulfide cells after five years of storage. Also, there had not been any early depletions of Gamma test cells stored under load, except for a few cells which were shown to have been externally shorted by mishandling. Further, no Gamma pacer had exhibited early battery depletion either in the Cordis simulated use test or in clinical use. Thus, at that time, Cordis had no reason to suspect that early battery depletion was a problem in Gamma cells.

Although Cordis did not link the feedthrough corrosion to cell self-discharge in 1980, it was concerned about this phenomenon and investigated its significance by contacting its feedthrough supplier, Fusite. At Fusite's suggestion, Cordis contacted Sandia Laboratory about a similar phenomenon discovered by Sandia in lithium sulfur dioxide cells and obtained available information on Sandia's experience.

Cordis did not establish a relationship between glass corrosion and potential Gamma cell early depletion based on the information known in 1980. Although corrosion of glass feedthroughs in lithium-sulfur dioxide cells was reported by Sandia Labs and found by Cordis in lithium-cupric sulfide cells, Cordis was not able to find in Gamma cells the lithium bridging discovered in the Sandia cells. Cordis found that feedthrough resistances of Gamma cells were not significantly reduced, except in a few cases in cells stored at temperatures near or above the boiling point of the Gamma cell electrolyte. These high temperature results were considered abnormal and not relevant to the normal operation of the Gamma cell at much lower temperatures.

Also, the lithium-sulfur dioxide cell studied by Sandia is significantly different from the lithium-cupric sulfide Gamma cell. In the early 1970's, Cordis had evaluated a lithium-sulfur dioxide cell manufactured by Power Conversion, Inc. as a possible pacer power source. Cordis abandoned this type of cell because the sulfur dioxide leaked from the pressurized cell and attacked the electronic circuitry. The lithium-sulfur dioxide cell also has a higher voltage (2.95 volts versus 2.10 volts). Thus, because of the knowledge that the two types of cells were quite different, Cordis did not expect that the failure mechanism discovered by Sandia would necessarily occur in the Gamma cell.

4. Addition of the Feedthrough Protectors

The addition of the polypropylene feedthrough protector to Gamma cells in 1980 was motivated primarily by concern about the possible loss of feedthrough seal integrity and consequent electrolyte leakage. This possible failure mechanism was also reported by Sandia based on corrosion in lithium sulfur dioxide cells. Cordis considered it possible that corrosion could eventually extend completely through the feedthrough and lead to loss of structural integrity. The possibility of early battery depletion was not given serious consideration because of the lack of early depletions in the field and the confidence Cordis had developed in lithium-cupric sulfide cells. Gamma pacers previously made with cells having unprotected feedthroughs were not reworked because Cordis considered the risk of sufficient corrosion of the glass to cause failure of the seal to be low.

The polypropylene protector is effective, but not perfect. Its addition has reduced the incidence of early battery depletions from about 9% to about 0.1% to date. However, the polypropylene protector depends on a tight compression seal against the feedthrough ferrule, glass insulator and center pin to be effective. Therefore, in August, 1982, Cordis implemented an improved protector consisting of a coating of polyimide which actually adheres to the feedthrough components.

The Mini-Gamma cell, which is a smaller version of the Gamma cell for use in the Mini-Gamma pacers, Model 340A, is still manufactured with the polypropylene feedthrough protector. The configurations of the feedthrough components of the Mini-Gamma cell do not allow the polyimide coating to be applied in a manner which would create an effective barrier against electrolyte contact.

5. The Early Depletion Problem

The initial explant of a Gamma pacer occurred in February, 1981, and was considered to be a random failure. The second explant occurred in July, 1981, and was also considered to be a random failure. Considering the large number of implanted Gamma pacers functioning within specifications at the time, classification of these failures as random was appropriate, particularly since Cordis was not able to determine the exact cause of the failures. All pacer manufacturers, including Cordis, receive a small number of failures which have no systematic cause and which are classified as random failures. Such random failures do not signal the need for any notification. Physicians are aware of the possibility of occasional, random failures and monitor all pacers to detect such failures. Random failures are also discussed in the labeling of Gamma series and other Cordis pacers.

If a significant number of failures occur for the same cause, they are no longer considered random failures and a notification or recall is initiated. Cordis has relied on a reliability prediction, prepared by Cordis Reliability Engineering for each new pacer model before its introduction, as a means for deciding if the incidence of failures has become significant. Thus, if the achieved reliability determined from monitoring of the Cordis pacer registry data for a particular pacer model drops significantly below the prediction for that model, Cordis notifies physicians about the situation and recommends an appropriate course of clinical action. Prior to use of reliability predictions, Cordis in 1975 issued a Notification on Kappa series pacers when two Kappa series pacers failed because of pin-hole corrosion through their hermetic, stainless steel cases. No additional failures were ever reported, and the physicians and patients receiving the notification were unnecessarily alarmed. Thus, Cordis does not react to a small number of failures with a Notification but analyzes each situation in terms of the applicable reliability prediction to determine its proper course of action.

Cordis therefore did not notify physicians in 1981 about early battery depletions in Gamma series pacers because the small number of early failures were consistent with the reliability prediction for Gamma pacers. It did, however, begin a series of investigations to try to establish a failure mechanism for these failures. The investigations were performed by Power Sources Engineering and Corporate Product Assurance with consultation from DuPont, M.I.T., Sandia Labs, and Cordis feedthrough manufacturers. Several hypotheses were considered in these investigations, and two were pursued with particular vigor.

One such hypothesis involved the formation of a soluble polysulfide complex of cupric sulfide which could migrate through the cell separator and react directly with the lithium, thereby creating an "internal" short and reducing useful cell capacity. Only one early depletion has been attributed to this failure mechanism.

The other hypothesis concerned the possibility that particles of cupric sulfide could migrate from the cathode through holes in the separator, resulting in a similar reduction in cell capacity. This mechanism has been confirmed as the cause for only two early cell depletions. However, to protect against this problem, more stringent inspection of the Pellon separator material was instituted in January, 1982, and an improved separator material, Celgard, was introduced in June, 1982.

6. Gamma Task Force

In June of 1983, when the number of Gamma pacers returned because of early battery depletion increased significantly, Cordis intensified efforts to establish the elusive cause of early Gamma cell depletions. In August 1983, a Gamma Task Force was assigned to define the extent of early Gamma battery depletions, determine the cause and recommend any necessary corrective actions. The Task Force reviewed all Gamma cell data and discovered an informal study performed on 200 reject Gamma cells between October, 1980, and July, 1982, which previously had not been reported to Cordis management. These cells, which had no feedthrough protection, were stored, with and without resistive loads, at 10 different temperatures. Increased temperature decreased the time until early depletion in these cells. Unfortunately, in addition to the results not being reported, there is no record of any analysis of failed cells from the study. The Task Force found seven cells which had depleted after 22 months of storage at 50° C. Analysis of these cells detected approximately 45% corrosion of the feedthrough glass and almost complete consumption of the lithium anode.

Cordis is embarrassed by the fact that the 200 cell study was not reported to management by the engineer who initiated and monitored the test or by the laboratory personnel who stored the units. Although analysis of the depleted cells would probably not have detected lithium bridging, the study provided evidence that early

Gamma cell depletions were directly related to the glass feedthrough corrosion which probably would have helped Cordis establish the failure mechanism earlier. If the results of this study had been reported in July 1982 and Cordis had acted upon the information, the shipment of 147 Gamma pacers with cells without feedthrough protection could have been prevented. As explained later, Cordis is taking corrective actions to assure in the future the prompt reporting of all technical data.

The Task Force completed its review of all available information about early Gamma cell depletions and issued its final report on November 30, 1983. It concluded that reaction of the electrolyte with the feedthrough glass insulator caused self-discharge through a lithium bridge, followed by reaction of the lithium with the glass, resulting in destruction of the lithium bridge and corrosion of the feedthrough glass. This conclusion was based primarily on the effectiveness of the polypropylene protector in preventing early battery depletion, rather than on direct evidence of lithium bridging.

7. Gamma Pacer Notification

As a result of the Task Force findings, on December 5, 1983, Cordis notified all affected physicians about the problem and recommended monthly monitoring of all Gamma series pacers with cells made before the addition of the polypropylene protector in October, 1980. Cordis records indicate that the Notification has been more than 95% effective and Cordis is continuing its efforts to increase its effectiveness. Also, Cordis is attempting to find lost-to-follow-up patients to assure that all patients with Gamma pacers receive the recommended monthly monitoring.

B. CORRECTIVE ACTIONS

Cordis has recognized the need for improvements in some of its policies and procedures as a result of reviewing the FDA's observations. Although formal Cordis policies and procedures were in effect, the changes will make them more detailed and more effective.

1) Product Service Reports (PSR's) - CSP 14-08-02

This CSP will be revised to improve the processing of all three types of PSR's: for pacers, for other sterile products and for repairable products.

a) The PSR forms will be changed to solicit information on the status of the patient and detailed information if there is a device-related serious injury or death. The PSR also requests specific information about whether or not any reported injury or death is device-related.

b) All PSR's which report a possible hazard, injury or death will be filed in a "Hazard Investigation" file until investigation by the Cordis Customer Service Department is completed. After completion of the investigation, all such PSR's will be filed in the permanent "Hazard" file, even if the hazard was not confirmed.

c) When an investigational product is released for sale, Clinical Research will provide a summary of all complaints received during the clinical investigation of the product for filing in the corporate PSR files Subsequent PSR's relating to the investigational devices will be filed in the corporate PSR files.

d) The Legal Department will assure that a PSR is generated whenever it receives notice of a possible liability suit alleging device malfunction.

e) A duplicate PSR file will be maintained at each divisional or affiliate manufacturing site where the Cordis product is made.

f) All PSR's will be numbered sequentially and logged as received in a manner that assures good traceability and accountability.

g) The Product Service Department will be required to follow-up on all PSR's to assure timely analysis and prompt reply to the user.

2) Control of Discrepant Materials - CSP/COP 14-03-04

The Material Review Record (MRR) form and associated policies and procedures will be revised to:

a) Require that the basis for disposition of a discrepant material be documented.

b) Require that the actual disposition be documented.

c) Require that before any deviation from an approved specification or process procedure that is allowed by the MRR is implemented, that it be qualified and the completion of the qualification be documented, or the reason why qualification is not required be documented.

d) Require documentation of a decision on the disposition of any parts or products made previously which might be affected by a change authorized by the MRR.

e) Permit delegation of approval authority under defined conditions.

3) Product Documentation Change Control - CSP 10-02-03

This policy will be revised to:

a) Require documentation of the qualification of any change or the reason why no qualification is required before implementation of the change.

b) Require documentation of a decision on the disposition of any affected part or product made prior to the change.

c) Require Regulatory Affairs review of all change requests for products which received FDA pre-market approval (510(k) or PMA) to assure that any required supplemental submissions are made and approved by FDA before the change is implemented.

4) Control and Reporting of Technical Data - CSP 11-03-01

This policy, currently titled "Technical Notebooks," will be revised to require each engineer to:

a) Record all technical data generated in a complete and understandable form.

b) Prepare a protocol stating the purpose of any technical study undertaken, giving a complete description of the samples and procedures to be used and stating a basis for judging whether the results are satisfactory.

c) Report regularly to two higher levels of management on all results of technical studies, including a discussion of the meaning of the results, a conclusion, recommendations for future work, etc.

5) Product Assurance Audits - CSP 14-01-05

This policy will be revised so that a product problem investigation will not be considered to be a Product Assurance Audit and records of the investigation will not be destroyed after the recommended actions are completed. Such records will be retained as permanent records and will be available to FDA during inspections relating to the problem.

6) Training

All personnel involved with activities affected by these changes in policy and procedure will be instructed in the reasons for the changes and, as necessary, will be instructed in how to comply with the new policies and procedures.

The preceding information is intended to provide a better organized and more complete response to the FD 483 reports than Cordis can provide with point-by-point responses alone. If, after review of this letter and the point-by-point responses, the FDA has any further questions, please call or write Cordis for further information.

In addition to preparing the accompanying responses to the two FD 483's relating to Gamma series pacers, Cordis is preparing point-by-point responses to the two FD 483's relating to polyurethane pacer leads and the FD 483 relating to the recent Cordis recall of catheters because of leaks at the hub connector. Cordis plans to submit these responses to FDA by July 1, 1984.

Sincerely yours,

Norman R. Weldon
President

Harold Hershenson
Executive Vice President

FDA Observation

(1) Cordis Standard Practice concerning "Receiving and Inspection of Incoming Material" dated September 20, 1983 (CSP 14-03-02) allows for the "Conditional Release" of components to production prior to the completion of the required inspections. This practice may result in the acceptance of finished devices having one or more marginal components due to economic influences.

Cordis Response

Cordis disagrees that the practice of "conditional release" results in the acceptance of finished devices with marginal components due to economic influences. It has always been Cordis policy not to compromise quality for economics and this policy applies fully to the use of conditionally released material.

"Conditional Releases" of materials allow needed materials to be used in production on a risk basis, when they are received too late for the normal Receiving Inspection testing and release cycle to be completed. The Cordis system for controlling Conditionally Released materials is defined in Cordis Standard Practice (CSP) 14-03-02, "Receiving and Inspection of Incoming Material" and Quality Assurance Operating Practice (QAOP) 111-04, "Monitoring and Controlling Conditionally Released Material" (Exhibits 1-1 and 1-2). These documents, which were provided to the Investigator, are intended to assure that devices manufactured with such materials are not released for sale before the conditionally released materials used in their manufacture meet all specified requirements. If any conditionally released material fails to meet specified requirements, the subassemblies or final devices containing this material must be reworked or scrapped. Cordis does not have any different or lower standard for acceptance of devices made with conditionally released materials than for other devices.

FDA Observation

(2) The protocol for the qualification of Northeast Electronics Corp., Milford, CT., coined lids with integral cut glass feedthroughs for Gamma cells (#82-02-008) states that, as part of the acceptance criteria for the lids, "There shall be no evidence of cracking, breaking, or loosening of parts" . However, the qualification report summary states that "Three lids, which had passed hermeticity testing, were found to have cracks in the glass. The exact origin of these cracks could not be determined." The qualification of the Northeast Lid was approved by the Product Engineering Team (PET) despite the lack of conformance with the qualification protocol. No explanation is provided for the qualification approval.

Cordis Response

Cordis agrees that the PET approved the qualification of Northeast lids with integral cut glass feedthroughs although three units had cracks and failed to meet the protocol for qualifying Northeast Electronics Corporation feedthroughs which states "there shall be no evidence of cracking... for the lids".

All qualification test units had passed hermeticity, thermal shock, visual, vibration and resistance testing as noted in the detailed QAQL worksheets (Exhibit 2-1) and the insignificance of the cracks is discussed in the Weidner memorandum (Exhibit 2-2). According to the PET members, two of whom are still employed at Cordis, the observed cracks in the three units were not severe and were considered unimportant. The PET.s main concern was cracking which could cause loss of hermeticity. Since the units had passed the hermeticity test, these cracks did not cause leakage. Under the circumstances, Cordis believes that the PET made the proper judgment that the cracks involved were not so severe as to fail the qualification of the vendor. However, the PET should have documented this reasoning when they qualified Northeast feedthroughs despite failure to conform with the protocol.

In retrospect, the PET.s judgment is confirmed in that approximately 100,000 battery cells with sealed feedthroughs from Northeast Electronics have been used in pacers; none has failed due to loss of hermeticity or any other failure mechanism attributed to feedthrough cracks.

FDA Observation

(3) On February 13, 1984, two [redacted] ([redacted]) rolls were noted stored horizontally partially inside a cardboard box with the upper portion of both rolls in direct contact with the stockroom floor in building 7G. A noticeable degree of dirt was present on the exposed surfaces and edges of both rolls. Two other [redacted] rolls without protective covering were noted in the stockroom.

Cordis Response

The portions of the [redacted] rolls found to be dirty during the FDA inspection of the stockroom have been cut off and scrapped. Stockroom management has been reminded to handle [redacted] rolls with care and to maintain their cleanliness. Also, Receiving Inspection management has been cautioned to re-wrap [redacted] rolls if the original wrapping is damaged.

The [redacted] rolls are cut into small squares for use in battery manufacture. Each square is visually inspected prior to use in a cell, and soiled pieces are rejected and scrapped. Therefore, no dirty [redacted] has been used in cell manufacture.

FDA Observation

(4) On February 15, 1984, at 10:20 a.m., the cupric sulfide powder Production Log Sheet showed a pre-completion entry for step 70, (relating to the addition of water after the reaction vessel heater is turned off). The addition of the water was scheduled for 11:20 a.m.; however, the Production Log Sheet misleadingly reflected that the water had already been added.

Cordis Response

Cordis agrees with the Investigator.s observation. The powder manufacturing operator has been reminded of the requirement for recording of processing times in the appropriate record only at the time an operation is carried out, and warned that failure to maintain accurate records would result in disciplinary action. A memorandum has been sent to all Power Sources personnel regarding this issue. (Exhibit 4-1).

FDA Observation

(22) Complaints pertaining to any hazard to safety are not immediately reviewed, evaluated, and investigated nor are they maintained in a separate portion of the complaint file. For example:

Cordis Response

Cordis policy CSP 14-08-02, "Product Service Reports" (Exhibit 22-1), details the requirements for receiving, evaluating, investigating and documenting reports related to product performance. This Cordis system is designed to assure that all incoming reports of alleged product malfunction or patient hazard are evaluated, investigated and fully documented in a timely manner.

The Product Service personnel first review the available details of each complaint received and record them on appropriate documents. They also judge, based upon their years of experience in dealing with medical reports and product investigations, whether a patient hazard, injury or death associated with the product has been alleged. If they conclude that a hazard or injury may have occurred, Cordis policy requires that they immediately investigate the matter with the patient.s physician, hospital, Cordis Sales Representative, etc. If a hazard or injury is confirmed, they are required to notify the Vice President of Product Assurance at once.

Contrary to the observation, Cordis does maintain a separate "Hazard File", which the investigator reviewed in detail. It has always been Cordis policy to place into that file all complaints in which a patient injury or hazard has been associated with a confirmed device malfunction.

FDA Observation

(a) Product Service Report (PSR) Number 56498 concerns an individual who "blacked out while driving car" whose pacer was "found to be dead". The suspect pacer (334A-5938) was explanted on October 7, 1983. The PSR was completed by a Cordis salesman on October 12, 1983. The pacer was returned to Cordis on October 18, 1983, and analyzed November 7-10, 1983, with the conclusion that the pacer failed because of early battery depletion (EBD). A health hazard assessment was not initiated until December 3, 1983, when this complaint was brought to the attention of Cordis officials by the Food and Drug Administration.

Cordis Response

Cordis agrees that PSR 56498 (Exhibit 22a-1) should have been evaluated relative to potential hazard promptly upon receipt in accordance with Cordis policy (CSP 14-08-02, Product Service Reports, Exhibit 22-1). This oversight on the part of the Product Service Department was discovered in a review of the Gamma pacer PSR file made in preparation of the Notification and brought to the attention of the Vice President of Corporate Product Assurance on December 2, 1983. He immediately ordered re-evaluation of this PSR. The hazard evaluation was completed and documented on December 12, 1983. On the basis of discussions with the attending physicians, it was concluded that the patient.s condition was not pacer-related (Exhibit 22a-1).

The Cordis employee responsible for the failure to conduct a prompt investigation of PSR 56498 was severely reprimanded. In addition, as discussed in the responses to Observations 23b, 25, and 27, the Product Service Department has been re-organized and the PSR system and forms have been revised to assure more timely and effective evaluations of potential hazards.

FDA Observation

(b) PSR Number 78621 concerns Pacer 334A-4214 that had a "rate decrease" and also was reported to be a "Runaway at 160-170 ppm." The pacer was explanted on October 18, 1983, and returned to Cordis on November 1, 1983. The pacer was analyzed on November 16, 1983, with the conclusion that the pacer failed due to EBD. A health hazard assessment was not initiated until December 16, 1983, after this complaint was brought to Cordis' attention during this inspection.

Cordis Response

PSR 78621 (Exhibit 22b-1) was reviewed by the Product Service Department; in their opinion it did not constitute a hazard, as asserted by the Investigator. The PSR contained two contradictory statements: (1) the pacer experienced rate decrease, (2) the pacer experienced a runaway at 160 to 170 ppm. It is apparent from examination of the EKG accompanying the PSR that the so-called runaway was caused by a brief episode of ventricular tachycardia which was not associated with the pacer. Statements written by the nurse on the EKG show that the patient was sleeping at the time, in no distress, easily aroused, and denied any blackout, chest pain or shortness of breath. Since the pacer was found to have failed due to early battery depletion, which would have been manifested by a rate decrease, it was concluded that the tachycardia was not pacer induced. In summary, there was no reason for the Product Service Department to consider this a hazard report; however, the Product Service representative should have documented the reason for not considering this PSR a hazard report.

FDA Observation

(c) PSR number 56152 concerns pacer 334A-6096 that was explanted on August 10, 1983, due to a rate decrease with a complaint that the patient experienced "dizzy spells". The pacer was returned to Cordis and analyzed on September 14, 1983. The pacer had a rate of 61.8 instead of 70.0. The analysis concluded that the pacer failed due to early battery depletion. No additional investigation has been conducted to determine if the dizzy spells were related to the pacer failure.

Cordis Response

The Product Service Department reviewed PSR 56152 (Exhibit 22c-1) which cited "dizzy spells" and decided it was not a hazard. The pacer was operating at 61.8 beats per minute when received by Cordis. That rate is so nearly normal that, in the Department.s judgment, the pacer could not have caused the dizziness. The pacer had been replaced uneventfully with another Cordis pacer.

Observation 22c states that no additional investigation was conducted to determine if dizzy spells were related to pacer failure. To the contrary, to confirm the Department.s original conclusion that this was not a patient hazard, the Product Service Representative discussed this PSR with the physician, Dr. M. Z. Abbassi (See Exhibit 22c-1). Dr. Abbassi stated that the patient came to the office for a routine check, which disclosed that there had been a rate decrease. The pacer was replaced promptly with no harm to the patient, and Dr. Abbassi stated that he did not believe the pacer had been hazardous to the patient.

FDA Observation

(23) (a) Cordis Standard Practice (CSP) Number 14-08-02 dated December 15, 1980, states that "The Cordis employee who first receives an oral or written report about the performance of a Cordis product shall promptly write a Product Service Report (PSR) (see attachment)". The attachment referred to is the Cordis in-house complaint handling form and not the similarly named form normally completed by the explanting physician or an associate. The majority of the approximately 248 complaints reviewed through December 31, 1983, did not include the Cordis in-house PSR.

Cordis Response

As required by Cordis procedure CSP 14-08-02 "Product Service Report" (Exhibit 22-1), employees who first receive an oral or written report about the performance of a Cordis product promptly write a Product Service Report (PSR). However, they do not write a PSR if one is returned with an explanted pacer.

Cordis has two PSR forms. One is titled "Product Service Report", with the parenthetical statement, "formerly called Out-of Service Report" (Exhibit 23a-1). A copy of this form is packaged with each pacer and is used by a physician to record pacer explant information for return with the explanted pacer to Cordis. The other PSR form is the "in-house" form (Exhibit 23a-2), used to report product performance for products other than pacers such as catheters, leads, etc. On rare occasion, the "in-house" PSR form is used to record a pacer report that is received verbally or to document receipt of an explanted pacer returned without a completed PSR. The majority of the 248 complaints cited in Observation 23a did not include the Cordis "in-house" PSR because, in most cases, a physician PSR had been received, analyzed and properly filed.

The investigator apparently interpreted the Cordis procedure to require generation of an "in house" PSR even if a physician PSR had been received. This is not the intent of the procedure and would involve unnecessary duplication. CQP 14-08-01, "Processing of Returned Cordis Products" (Exhibit 23a-3) describes the two PSR forms. CSP 14-08-02 has been revised to clarify the use of the two PSR forms.

FDA Observation

(b) CSP No. 14-08-02 also states that Product Service "Alerts the Vice President of Product Assurance immediately regarding any report alleging injury, suspected related death, or a health hazard". The Vice President of Product Assurance was not aware of the three complaints specified in Item (1) nor is there any documentation attesting that the Vice President of Product Assurance had been alerted.

Cordis Response

As explained in the responses to Observations 22b and 22c, PSR.s 56152 and 78621 were evaluated by the Product Service Department and were not judged to be hazards; consequently, there was no requirement to inform the Vice President of Corporate Product Assurance about these two PSR.s.

Cordis does agree, as stated in the response to Observation 22a, that the evaluation of PSR 56498 for potential hazard was not investigated promptly and that the Vice President of Corporate Product Assurance was not informed of that PSR in accordance with Cordis standard procedure. Cordis has reorganized the Product Service Department, and revised the PSR system and forms to insure more timely and effective evaluation of potential hazards and prompt notification of the Vice President of Corporate Product Assurance.

FDA Observation

(24) On December 25, 1983, it was brought to the attention of a Cordis Sales Representative that Gamma pacer 334A-2511 had malfunctioned. Surgery was scheduled at the Pembroke Pines Hospital, Pembroke Pines, FL., on the following day. The Sales Representative visited the hospital on December 26, 1983, and obtained the malfunctioning pacer. However, a PSR was not submitted to Product Service by the Sales Representative and the pacer was not sent to Cordis for evaluation until February 6, 1984. According to attending physicians, the pacer failure resulted in the patient's cardiac arrest.

Cordis Response

The observation is correct relative to the long delay by the salesman in reporting the complaint and returning the pacer for analysis. The responsibility of salesmen to comply with the requirements of the Cordis PSR procedure was re-explained to the Sales Representative by the Vice President of Corporate Product Assurance and the Manager of National Sales.

The Product Service Department first learned of the problem on February 1, 1984, when they received a letter dated January 17, 1984, from the patient.s daughter. The Department generated a PSR and commenced investigation immediately. The results of the investigation are documented in PSR 79528, (Exhibit 24-1).

The investigation determined that the patient had been lost-to-follow up since July, 1983. She had not responded to requests for examination by either her family physician or the cardiologist. The cardiologist stated that, given the fact that the patient.s status had not been monitored for such a long period, it was not possible to determine whether her condition was related to pacer failure.

FDA Observation

(25) The PSR form is not designed to elicit specifically any adverse affects that may have been experienced by a patient as a result of a product failure. Consequently, the Product Service Department cannot readily determine if an investigation is warranted to assure that patient safety was not compromised.

Cordis Response

The PSR form for pacers (Exhibit 23a-1), has been in use, with minor variations, for some years. It requests pertinent information on pacer performance and patient status, including representative EKG records and other information if the pacer is believed to be operating outside of specifications. Cordis believes that the present form has usually provided adequate information to make proper hazard evaluations. However, in response to the observation, Cordis has revised the form (Exhibit 25-1) to request specific patient status information to assist the Customer Service Department in determining whether further investigation of the clinical complaint may be warranted.

FDA Observation

(26) As of February 1, 1984, there were a total of 270 expired patients that had Gamma pacers subject to the December 5, 1983, Gamma notification. Prior to this inspection, no effort had been made to determine if the recognized pacer early battery depletion failure mechanism could have resulted in a patient death that may have been mistakenly attributed to non-pacer related causes because a physician had no reason to suspect early pacer failure.

Cordis Response

From experience, Cordis has learned that very few deaths of pacer patients are related to pacer malfunction. Pacer patients are generally old (average age about 70) and usually have a variety of medical problems in addition to their need for pacer support.

Physicians know that any pacer, whether or not it is involved in a notification, can fail at any time. For that reason, they monitor pacers routinely. If a pacer patient dies, the physician always considers pacer malfunction in his investigation into the cause of death. Whenever a physician encounters a death which he believes may be pacer-related, he almost invariably informs Cordis in a timely manner. Cordis investigates all such reports thoroughly. If Cordis were instead to investigate every report of a patient death, Customer Service personnel would constantly be involved in unnecessary investigations rather than concentrating on the reports indicating pacer-related deaths or other hazards.

Cordis confirmed the appropriateness of this policy by investigating 45 reports of deaths among patients with Gamma pacers. The Product Service Department did not discover a single patient death that could be attibuted to pacer malfunction. This investigation was summarized in a memorandum of January 19, 1984 to Mr. Pagones (Exhibit 26-1).

FDA Observation

(27) Prior to this inspection, a health hazard analysis was not done for the following Product Service Reports:

Product Service Report No.	Date Pacer Received	Model # and Serial # of Pacer	Patient Complaint
56499	10/18/83	334A-2348	"symptoms"
75559	1/29/82	33B7-320	"dizzy spells"
56152	8/31/83	334A-6096	"dizzy spells"
77222	2/16/83	334A-3212	"fatigue"
77435	4/14/83	337A-246	"unresponsive intermittently"

Cordis Response

The Product Service Department did evaluate each of the five PSR.s referenced in this Observation (Exhibit 27-1 through 27-5). Although the PSRs contained information which could indicate possible potential hazard or injury, based on the total content of each PSR and their professional experience, the Department judged that a health hazard analysis was unnecessary in these five cases.

In response to the Investigator.s concerns, Cordis contacted the original complainants and confirmed that none of the five reports represented a patient hazard or injury. The results of these additional investigations were provided to the Investigator and are attached to the PSR.s.

Cordis has now changed its policy and procedures for handling PSR.s and has instructed personnel to investigate all complaints with an indication of possible patient hazard or injury unless they have been specifically reported to be not pacer related. The revised PSR form specifically requests the reporting physician to indicate whether or not death or serious injury is considered pacer-related (See Exhibit 25-1).

FDA Observation

(28) Cordis returned goods procedure requires that returned implantable devices be held in the returned goods area until the initial paperwork is processed by the Product Service Department. As individual receiving tickets are completed for each returned device, there is no system in effect that can readily identify the status of each device, i.e., device in returned goods area awaiting release to failure analysis, device sent to failure analysis, etc.

Cordis Response

Cordis disagrees with the Investigator.s observation. Cordis has a computerized system to track the status of returned implantable devices through the failure investigation cycle. As detailed in CQP 14-08-01 (Exhibit 23a-3), a receiving ticket is prepared and sent to the Product Service Department at the time the device is sent to decontamination. The device remains in the decontamination area until Product Service completes the associated paperwork and sends it to Returned Goods for attachment to the device. In addition to this paperwork, Product Service generates a computer "tracking" record which traces the status of the returned device throughout the investigation cycle. This tracking system enables Cordis to locate and identify the status of any returned device. A copy of the Returned Pacer Data Entry Screen is attached. (Exhibit 28-1). If the Investigator had discussed this observation with Cordis prior to inclusion in the FD 483, Cordis would have provided information about this tracking system.

FDA Observation

(43) In an August 28, 1980 memorandum from Stan Solomon to Mr. Dehaan, Mr. Hart, Mr. Jimenez, and Mr. Withers, concerning a telephone conversation on feedthrough reactivity held between Mr. Solomon and Mr. Ben Bowsky, Fusite Corporation, Mr. Solomon learned that Mr. Bowsky was aware of the feedthrough reactivity in that Mr. Bowsky stated, "That seal degradation was a electrochemical process involving exchange between the lithium and the sodium and potassium of the glass."

In this conversation, Mr. Solomon informed Mr. Bowsky's that Cordis had determined that the glass received from Fusite consisted of a crystalline and a smooth phase with these glasses having different compositions. Although Mr. Bowsky stated that neither phase was preferentially more reactive than the other, Cordis did not conduct any qualification testing to specifically determine if one phase was, in fact, preferentially more reactive than the other.

Mr. Solomon next contacted Samuel C. Levy, Head, Battery Program, Sandia Laboratories, Albuquerque, New Mexico, to discuss Cordis' findings with respect to feedthrough corrosion and loss of feedthrough glass resistance. Dr. Levy stated that his studies involved a lithium sulphur dioxide cell in which he discovered two failure mechanisms: stress cracking and the formation of lithium bridges within feedthrough glass leading to self-discharge.

(44) In a memorandum dated September 15, 1980, from Mr. Solomon and from Mr. DeHaan re: "Trip Report on Visit to Sandia Laboratories, Albuquerque, N. Mexico", one of the conclusions drawn in this report is that, "Of the two aspects of the corrosion reaction (1) vertical degradation leading to potential stresses and mechanical failure of the feedthru, and (2) formation of conductive bridges between terminals, it appears that the latter is of more concern in the Cordis cell system. Evaluation of this is essential for prediction of future integrity of all feedthrus."

Cordis Response

The Investigator.s quotations from the memorandum of August 28, 1980 (Exhibit 43-1) and the trip report of September 15, 1980 (Exhibit 43-2), are correct and reflect Cordis efforts to understand the interaction of electrolyte with the glass feedthrough insulator in Gamma cells.

As recorded in the memorandum of August 28, Mr. Bowsky.s statement concerning seal degradation referred to the results of Sandia Lab.s investigations into lithium-sulfur dioxide cell failures. He did not state that the Fusite feedthroughs supplied to Cordis were susceptible to such degradation.

Mr. Bowsky.s response to Cordis. observation that the Fusite glass had two phases was not only that neither phase was preferentially reactive but also that biphasic glass is more resistant than single phase glass. Further, the increased resistance of biphasic glass to chemical attack is supported by U.S. Patent 4308323 (Exhibit 43-3), issued November 10, 1980 to Emerson Electric Co., the parent firm of Fusite, which states, "It has been discovered that by using two or more glasses of distinctly different electrical/chemical properties, the resistance of the seal to attack by chemicals corrosive to glass can be greatly enhanced." Under the circumstances, there appeared to be no need for qualification testing by Cordis to determine if one glass phase was more reactive than the other, as suggested in this observation.

As both quoted memoranda indicated, the Sandia experience showed two potential concerns with the Gamma feedthroughs - mechanical failure and loss of resistance due to formation of conductive bridges. Cordis studied both potential failure mechanisms in the Gamma cell.

As to mechanical failure, Cordis studied Gamma cells stored at various conditions and determined that the feedthrough glass insulator was attacked by electrolyte, causing concern about eventual loss of hermeticity after long service. Although Cordis found no stress cracking of Gamma feedthroughs of the type described by Dr. Levy as a failure mechanism in lithium-sulfur dioxide cells, it added the [redacted] feedthrough protector because of concern that the corrosion observed might eventually lead to loss of hermeticity.

As to the possibility of conductive bridges forming in the feedthrough, Cordis studied and tested for this in 1980. However, in view of the absence of a significant number of failures of Gamma cells at that time, and the absence of any direct evidence that such conductive bridges formed, Cordis did not identify this as a problem in the Gamma cell. Cordis still has not been able to establish by direct evidence that lithium bridging is a failure mechanism in Gamma cells as Sandia Labs established in the lithium-sulfur dioxide cell. The almost complete absence of early depletions in Gamma cells with [redacted] feedthrough protectors provided indirect evidence on which Cordis based its conclusion in 1983 that lithium bridging caused the early depletions of Gamma cells.

FDA Observation

(45) Based on the above reports and other Cordis reports demonstrating feedthrough corrosion and high feedthrough conductivity, polypropylene was selected to protect the glass insulator from lithium attack beginning with Gamma cell lot number 4180 (October, 1980).

Cordis Response

Contrary to the Investigator.s observation, Cordis implemented the polypropylene protector on Gamma cell feedthroughs in 1980 to protect against the possible loss of feedthrough structural integrity through long term corrosion by the electrolyte. At that time, Cordis had no evidence that corrosion of the Gamma feedthrough glass at body temperature caused high feedthrough conductivity or was related to self-discharge of Gamma cells.

Although a lithium bridging model in a pressurized lithium-sulfur dioxide cell had been reported by Levy of Sandia, it was not confirmed by Cordis in Gamma lithium-cupric sulfide cells. Only four experimental cells stored at the highly elevated temperature of 70°C to 90°C, were found to have lowered feedthrough resistance in 1980. Many other cells tested at various lower temperatures had acceptable feedthrough resistance although glass corrosion had occurred. Further, in 1980 there had been no early battery depletions in implanted or in-vitro pacers.

FDA Observation

(46) In spite of the data presented above and other information available to Cordis which documented the internal discharge mechanism of Gamma cells which results in early battery depletion, approximately 6,327 pacers which incorporated cells with unprotected feedthroughs were distributed from November, 1980 through August, 1983 after the Gamma cell design was improved to minimize or eliminate feedthrough corrosion and loss of resistance.

Cordis Response

Cordis disagrees with the observation that it had information before August, 1983 documenting the internal discharge mechanism which resulted in early Gamma battery depletion. Although lithium bridging had been reported in lithium-sulfur dioxide cells by Sandia Labs in 1980, it was not established as a failure mechanism in Gamma cells until November, 1983. While glass corrosion was observed in the Gamma feedthroughs in 1980, it was not found to cause loss of resistance except in a small number of cells stored at highly elevated temperatures. The [redacted] feedthrough protector was added to the Gamma cell in October, 1980 to prevent corrosion of the glass because of concern that it might eventually lead to loss of hermeticity. The effectiveness of the polypropylene protector in preventing early depletions subsequently provided the evidence that loss of feedthrough resistance must have occurred intermittently and caused early Gamma cell depletion. However, Cordis did not reach this conclusion until November, 1983.

The first explant of a Gamma pacer for early battery depletion occurred in July, 1981. If Cordis had discontinued shipment of Gamma pacers without feedthrough protectors when this first explant occurred, the shipment of 1115 such pacers after that date would have been prevented. However, at that time, the early depletion was considered to be a random failure because analysis had not established any systematic cause. Isolated, unexplained failures are unfortunately experienced routinely by Cordis and other pacer manufacturers, and neither Cordis nor any other manufacturer considers such failures as justifying discontinuance of shipment of the pacer models involved.

In August, 1983, Cordis management learned of a study of Gamma cells which had been initiated in October, 1980 and discontinued in July, 1982 without any report of the results. The study involved storage at various temperatures of 200 Gamma cells, rejected from production for various reasons. By the end of the study, all the units stored at 50°C had depleted in 21 months. This information might have helped establish the cause of early Gamma battery depletion sooner. Assuming that Cordis would have immediately discontinued the distribution of Gamma pacers without feedthrough protection in July, 1982, the shipment of 147 such pacers shipped after that date would have been prevented.

Cordis has reprimanded the Power Sources engineer who performed the 200 cell study without reporting the results to his supervisors. Also, Cordis will issue a new corporate policy to assure that all technical data is reported promptly to at least two levels of supervision.

FDA Observation

(47) The use of [redacted] to protect the feedthrough insulator is questionable and may not in all instances afford sufficient protection of the feedthrough insulator to prevent corrosion and feedthrough loss of resistance. Chemical and Physical Quality Assurance report # 23-03536 dated December 10, 1982 states that "In a Fusite control complete protection was not achieved with mild corrosion occurring under the [redacted] protector. This variability is consistent with previous studies on polypropylene protectors and accounted for the recommendation to use [redacted]s a mask." Cordis continues to use polypropylene protected Fusite feedthroughs in the Mini-Gamma cells.

Cordis Response

Cordis disagrees that the use of [redacted] to protect the feedthrough insulator is questionable and may not in all instances afford sufficient protection of the feedthrough insulator to prevent corrosion and feedthrough loss of resistance. In all cases in which the [redacted] protector is sealed tightly to the feedthrough, little or no glass corrosion has occurred under conditions known to cause corrosion of unprotected feedthroughs. The [redacted] protector was qualified in several studies. (See CPCL Reports 23-02060, 23-02066, 23-02203, and 23-02710, Exhibits 47-1 to 47-4). In CPCL Report 23-3536 (Exhibit 47-5), cited by the Investigator, the analyst noted "mild corrosion" after 14 days at 70ºC and observed that the protector was "not well bonded".

The effectiveness of the [redacted] protector relies on mechanical compression to form a liquid-tight seal against the feedthrough components, and it is evident that the seal will be compromised if this tight compression is not achieved. However, only about 0.1% of the Gamma pacers with cells having [redacted] feedthrough protectors have exhibited early battery depletion, compared to about 8% of the Gamma pacers without such protection.

Cordis continues to use the [redacted] protector in the Mini-Gamma cells because the physical shapes of the Mini-Gamma lid, ferrule and feedthrough in these cells do not permit an effective application of polyimide.

FDA Observation

(109) A two-page memorandum dated August 19, 1983, from J. Pagones, Vice President, Corporate Product Assurance, to N. Weldon, H. Hershenson, F. Fischer, R. Smolowitz, B. Nickerson, K. Jones, S. Saulson, R. Spencer, D. Colbert, J. Schwoebel, D. Bump, R. Gjertson, D. Hart, O. Jimenez, H. Tataria, and P. Watson, titled "Gamma Cells and Gamma Pacers - Task Force" which identified eight factors that the Task Force should consider or investigate relating to the Gamma pacer early battery depletion situation, was revised, on or about December 1, 1983. The revised memorandum (one page); however, has the August 19, 1983, date and deletes the aforementioned eight factors. The revised memorandum has the same distribution as the original; however, Mr. Watson, denied receiving a copy of this memorandum. The other individuals were not asked if they had received the one-page memorandum. FDA requested the Task Force assignment memorandum on December 3, 1983, and the one page revised memorandum was provided by Mr. Pagones on December 7, 1983.

Cordis Response

The observation is correct that Mr. Pagones prepared a revised one page version of the two page Task Force memorandum of August 19, 1983. This version was made to delete portions of the memorandum which were considered tentative and no longer applicable in December, 1983. Mr. Pagones erroneously prepared the revised memorandum with the original August 19, 1983 date and without any indication that it was a new, revised document. The revised Memorandum was given to the Investigator on December 7, 1983 by Mr. Schwoebel, former Cordis Manager of Regulatory Affairs. No copies were distributed to the persons who received the original Memorandum. On January 23, 1984, when the Investigator requested Mr. Watson.s copy of the Task Force Assignment memorandum, it was discovered that the one page revision had not been distributed to Mr. Watson and a copy of it was obtained for his files on that date. After further consideration, however, the existence of the two versions of the memorandum was recognized by Mr. Pagones to be incorrect and potentially misleading. Mr. Pagones brought this situation to the attention of his management. It was decided that the situation must be explained to FDA and this was done by Mr. Pagones in his memorandum to Mr. Spanioli of January 23, 1984 and his discussion of the situation with him on January 24, 1984. Copies of both versions of the Task Force Memorandum and Mr. Pagones. written memorandum of January 23, 1984, are attached as Exhibits 109-1, 109-2 and 109-3.

This situation represents an unfortunate error on the part of Mr. Pagones which was corrected by him as soon and as fully as possible. What occurred was not consistent with Cordis policy and was not known to Mr. Pagones. superiors prior to January 23, 1984. When it became known to management, Mr. Pagones and others in the company were made aware that such practices are not acceptable.

FDA Observation

(110) Cordis Gamma pacers notification letter dated December 5, 1983, stated that early battery depletions had occurred in 2.1% of the pacers subject to the notification. However, Cordis records show that as of November 30, 1983, the early battery depletion rate was actuallyt 2.5%.

Cordis Response

Receipt, failure analysis, review, input of data into the computer and final statistical analysis of field returns takes approximately 20 to 30 days to complete. Cordis submitted the draft Notification Letter to the printer on November 28, 1983. On that date, an October 31, 1983 summary was the last complete statistical analysis available on Gamma Field Returns and it provided the 2.1% value quoted in the December 5, 1983 Notification.

In retrospect, October 31, 1983 should have been stated in the Notification letter as the date when the 2.1% value was determined. The April 18, 1984 update to the Notification (Exhibit 110-1) clarified this point, indicating that the percent of failures was 2.1% as of October 31, 1983 and 7.5% as of March 31, 1984.

FDA Observation

(111) Examination of the notification/recall distribution accountability data revealed that all pacers incorporating suspect cells had not been identified. Further review of records by Cordis uncovered an additional 60 pacers that included suspect cells. Two of these pacers were Custom or "Engineering Order" pacers - Model number EO 306.

Cordis Response

Cordis agrees that on December 5, 1983, the date it mailed the Notification to physicians, the computer data base was not 100% accurate. As explained to the Investigator, the data base had only recently been completed by manual keying of over 2 million entries. Such a massive effort understandably resulted in data errors which Cordis subsequently identified and corrected as quickly as possible. Cordis provided the Investigator with a copy of a 5 page report, summarizing efforts to correct the data base and providing the correct results (Exhibit 111-1).

FDA Observation

(112) The notification cover letter dated December 14, 1983, states that, "Information received from other physicians indicate that you are following the additional patient(s) on attached list". This letter is misleading in that the "additional patient(s)" were determined due to FDA evaluation of accountability data and not from "Information received from other physicians".

Cordis Response

Cordis agrees that the December 14, 1983 letter to physicians, advising them of additional pacers subject to the Notification incorrectly reflected that the data had been obtained from other physicians. The letter identified 41 additional pacers which Cordis. Product Assurance staff had located through computer data base checks, which were accelerated as a result of questions raised by FDA.

FDA Observation

(113) Device history record (TRAVEL CARD ~~route sheet~~) for pacer 334A/1708 shows that cells from lot 1480 were used on May 2, 1980, and were replaced on June 4, 1980 by cells from lot 1880. However, the computer printout dated December 5, 1983, titled "All Gamma Pacers with Batteries prior to lot 4280" shows that pacer 334A/1708 contains cells from lot 1480.

Cordis Response

This observation is correct. The original cells, which were from lot 1480, were removed during a rework operation and new cells from lot 1880 were installed. The change was not entered into the computer record for this pacer. However, this pacer was already on the Notification list since both sets of cells used were from the Notification cell lots.

An extensive review of the data base for this type of problem was conducted by Cordis after this error was discovered and additional unidentified pacer cell replacements were found, resulting in an extension of the Notification list.

FDA Observation

(114) The investigation of the early battery depletion failure mechanism concerning Gamma Series pacers as it relates to processing deviations was treated as an internal audit rather than a complaint investigation (as of March 19, 1984, 574 confirmed and suspected complaints had been received) or as a device failure investigation. All official copies of the failure investigation report were destroyed. After the firm had been advised that the failure to provide a report of their Gamma cell investigation was considered to be an inspectional refusal, a copy of the report was provided. This copy was provided even though Cordis had advised that all copies had been destroyed.

Cordis Response

The investigation referenced in this observation, was conducted in September, 1983 by a Corporate Regulatory Affairs Auditor at the request of Mr. Pagones, Vice President of Product Assurance. The purpose of the investigation was to identify any possible processing or component deviations that could be contributing to the early battery depletion of Gamma cells. It was published in September, 1983 and designated a "Special Audit" by Mr. Schwoebel, former Cordis Manager of Regulatory Affairs.

Cordis internal audits are comprehensive and candid reviews of system faults and are meant for internal distribution only. It is Cordis policy to destroy all copies of audit reports after the conditions cited have been evaluated and/or corrected.

All official copies of this "Special Audit" Report were destroyed per Company policy more than 5 weeks before the FDA inspection commenced. When the Investigator requested a copy of the audit report, he was given copies of the destruction records (Exhibit 114-1). An unauthorized draft copy, clearly marked as such, was subsequently located by Mr. Schwoebel on 12/7/83. Retention of this draft copy of the report represented a failure on Mr. Schwoebel.s part to follow Cordis procedures as to an investigation which Mr. Schwoebel had designated as covered by the internal audit procedure. The draft copy nonetheless was provided to the Investigator by Cordis to comply as fully as possible under the circumstances with his request.

In retrospect, Cordis concurs with the observation that this was an investigation of a field problem and should not have been treated as an internal audit. In the future, such investigations will be maintained as records pertaining to the devices being investigated and will be available for FDA review. The Company policy on internal audits will be changed to state that investigations of product complaints or product failures will not be classified as internal audits.

FDA Observation

1. (a) On October 3, 1980, H. Tataria and F. Arbelaez, requested through Service Request #80-10-002, 302756 that a study involving 200 Gamma cells be carried out by the Qualification Laboratory whereby 20 cells each were to be stored at temperatures of 25°, 30°, 40°, 50°, 60°, 70°, 75°, 80°, 85° & 90° C, with 10 cells in each group to be placed on 100K load and the remaining cells kept at no load. The Service Request description reads "Store the Gamma cells as shown below to characterise feedthrough at different temp. Read voltage once a week until 1.0 volt is reached."

Reportedly, no written reports were prepared concerning this study during its duration. The study was terminated on October 7, 1982. As a result of the large number of Gamma pacer field failures attributed to early battery depletion in middle of 1983, this data was resurrected and evaluated as described in a memorandum dated December 19, 1983, from R.D. Gjertson, which states, in effect, that based on the 200 cell test data, the predicted Mean Time to Failure extrapolated to 37° C (body temperature) is 32.1 months. This memorandum also states that, "Accelerated thermal life testing has shown a very high degree of correlation to body use conditions."

There is no written documentation which explains why the data generated from this 200 cell study was not evaluated until the middle of 1983 considering that significant data may have been available earlier.

The following chart lists examples of the cells in the study that failed:

Temperature ° C	Cell #	Unloaded Voltage Reading (Spec. 2.14-2.20)	100K Load Voltage Reading	Date
50	194	2.076		10/15/81
50	191	2.097		10/22/81
50	220		2.083	10/22/81
60	434		2.078	4/30/81
60	387		.0180	6/4/81
60	320	2.099		6/18/81
70	200	2.062		12/31/80
70	369	2.076		1/22/81
70	226		2.055	2/5/81
75	154	2.095		1/8/81
75	179		2.099	1/8/81
75	486	2.088		1/15/81
80	344	2.087		12/11/80
80	382	2.094		12/18/80
80	406	2.094		12/22/80
85	93		1.994	12/1/80
85	410	2.085		12/8/80
85	70		2.075	12/8/80
90	311		2.082	12/4/80
90	128		2.092	12/4/80
90	304	2.080		12/8/80

Cordis Response

Cordis agrees with the observation which describes a study conducted from 1980 to 1982 on 200 Gamma cells stored at varying temperatures.

On October 3, 1980, Mr. Harshard Tataria, a Cordis power sources engineer, instituted a study to characterize the effects of elevated temperatures on Gamma cell performance. He generated Cordis Service Request 80-10-002, dated October 3, 1980 (Exhibit 1a-1), which requested the Cordis Qualification Laboratory to store 200 Gamma cells at 10 different temperatures and monitor voltage weekly until 1.0 volt was reached.

According to Mr. Tataria, the test cells were all rejects from various production lots. They had been rejected for defects such as feedthrough glass cracks, bent center conductors, low electrolyte, etc., some of which may affect the validity of the results obtained. Mr. Tataria did not keep a record of the lot numbers of the cells.

During the study, which began on October 6, 1980, Mr. Tataria occasionally examined the results of the voltage measurements and observed that Gamma cells stored at highly elevated temperatures (with or without load) dropped in voltage, while cells stored at temperatures near body temperature (37°C) functioned normally. In a concurrent study, polypropylene protected Gamma cells (See Tataria memo dated September 4, 1981, Exhibit 1a-2), exhibited no such voltage drops. Mr. Tataria states that he therefore concluded that high temperature adversely affects the life of non-protected lithium cupric sulfide cells. Mr. Tataria also states that he at some point orally informed his immediate supervisor (Mr. DeHaan) of his findings. Mr. DeHaan does not recall any such oral report. In any case, Mr. Tataria did not write a report to his superiors about his findings as he should have done. Cordis is revising the policy on recording and control of technical data to require periodic written reports to two levels of supervision on all results of technical investigations.

In July 1982, the Qualification Laboratory discontinued the study. Although the weekly voltage measurements had been recorded in a notebook, neither the laboratory personnel nor Mr. Tataria reported the results of this study to Cordis management at that time. The significance of this study was not appreciated at that time because there were not yet any appreciable number of field failures of Gamma cells. Again, the new Cordis policy described above would have required a report be made in writing to two levels of supervision.

In August 1983, Mr. Tataria brought the existence of this study to the attention of the Cordis Gamma Task Force which had convened in July 1983 to investigate the increasing number of early battery depletions observed in implanted Gamma pacers. Dr. Don Bump of Cordis Power Source Engineering immediately examined the data to determine if the observed failure rates followed the Arrhenius Law. Although the time to depletion decreased with higher temperature, the curve was not linear as predicted by the Arrhenius Law (See Dr. Bump's graphs dated 8/9/83 and 8/10/83 (Exhibit 1a-3).

Had the test results been brought to the attention of Cordis management prior to August 1983, they probably would have helped establish earlier that the early depletion of Gamma cells was related to corrosion of unprotected feedthroughs. Cordis considers Mr. Tataria.s performance in conducting this study seriously deficient and he has been severely reprimanded.

In addition to requiring the prompt reporting of results to two levels of supervision, Cordis is revising its policy concerning the collection and reporting of technical data to require preparation of a protocol prior to start of technical studies which establishes the purpose of the study, definitions of the materials and procedures to be followed, and a definition of acceptable results.

FDA Observation

(b) Of the approximately 140 cells that were kept on this test until failure, only seven were destructively analyzed to determine the cause of failure. These seven cells were analyzed on August 18, 1983, and were found to have in excess of 40% glass corrosion.

Cordis Response

In August 1983, the Task Force searched for cells from the study but the only cells found were seven cells from the 50°C group. These cells were immediately analyzed. CPCL Report 23-03877 (Exhibit 1b-1) confirmed that the cells were depleted. Feedthrough glass corrosion was detected but no cause was established for the early depletions. This type of analysis should have been performed on the cells as they depleted during the course of the study. The new procedures described above would require that this be done.

FDA Observation

(c) The batch number(s) of these cells is not recorded with the test data.

Cordis Response

Cordis agrees that the batch numbers of the 200 cells were not recorded. However, the seven cells analyzed in April 1983 from the 50°C population were from cell lot 2280, as documented in the laboratory report. The Cordis policy revisions discussed above will emphasize the need to record all pertinent data.

FDA Observation

2. (a) Production Delivery Slip dated November 3, 1980, pertains to the shipment of 351 Gamma cells (lot 4180A) from the battery manufacturing plant to the pacer production line. This lot included both cells with and without polypropylene protected feedthroughs. However, the polypropylene protection to the cell feedthrough was not approved until April 6, 1981, as shown in the Qualification Laboratory Report (#80-10-003). There is no documentation to show that pacers manufactured with these cells were not distributed prior to the approval date of the polypropylene qualification.

Cordis Response

Twelve Gamma pacers with cells having polypropylene protection were distributed prior to formal approval of the qualification of the addition of polypropylene protectors. The qualification tests of the polypropylene separator were successfully completed as reported on December 17, 1980, in CPCL Report 23-02203 (Exhibit 2a-1), although the Project Engineering Team did not sign the formal qualification statement for polypropylene on hermetic cells until April 6, 1981.

The pacers which contained polypropylene protected cells should have been quarantined until the qualification had been approved by the PET. Cordis policy on documentation control requires that any products made with unqualified components shall be quarantined until formal qualification approval of the component is granted. Cordis will emphasize to appropriate personnel the need to comply with this policy.

Item 2

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May 29, 1985

The Honorable H. John Heinz, III
Chairman, Special Committee on Aging
G-33 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Senator Heinz:

On behalf of Cordis Corporation, I would like to comment for the record on some of the issues raised during the Committee's May 10 hearing. Specifically, I refer to portions of the testimony about Cordis presented by FDA Supervisory Inspector James Casey and Investigator Victor Spanioli. Fairness and accuracy require that the Committee also consider the Company's position on these matters. I will discuss each point in the order it was presented:

1. The Company acknowledges that it distributed 6327 Gamma pacers with unprotected battery feedthroughs after October 1980, at which time the battery design was changed by adding a polypropylene protector. However, there is no basis for any inference to be drawn that the Company knowingly, much less willfully, marketed these products after it had reason to believe that they might be subject to potential early battery depletion. That simply was not the case.

As explained in response to the FDA's observation, Cordis engineers first observed minor glass corrosion in Gamma battery feedthroughs in 1980. However, extensive testing revealed that the corrosion, except in a small number of cells stored at highly elevated temperatures, did not affect battery performance. Because the first field failure of a Gamma pacer due to early battery depletion did not occur until July 1981, Cordis could not have known of the potential for early battery depletion at the time the change was made in October 1980. The addition of the polypropylene protector to the battery feedthrough was intended solely to assure the continued hermeticity of the cell. While accomplishing that purpose, the polypropylene was subsequently determined to produce an unexpected added benefit--a dramatic reduction in early depletions of Gamma pacers with batteries manufactured after October 1980. This fact, which did not become clear until November 1983, provided the first conclusive evidence that the original Gamma cell depletions were due to lithium bridging which caused intermittent loss of feedthrough resistance.

Had Cordis discontinued shipment of the original Gamma pacers in July 1981, with the first report of a field failure due to early battery depletion, 1115 such units would not have been distributed. However, the analysis of the one returned pacer did not establish a systematic cause and the problem, therefore, had to be considered a random failure. Such isolated, unexplained failures are unfortunate but not uncommon occurrences associated with all high-technology devices. Neither Cordis nor any other manufactuer discontinues shipments of product based on such isolated failures. The cause of the Gamma early battery depletions was not established by Cordis until November 1983 because the mechanism was so difficult to detect. At the time, Cordis took all appropriate steps to deal with the problem.

2. Testimony indicated that the Company had made no effort to investigate the cause of death of any of the 270 expired patients who were paced by a Gamma unit subject to the December 1983 notification. While true, this action is consistent with industry practice not to investigate unless the physician reports that the pacer may have malfunctioned and may have contributed to the patient's problem.

Experience has shown that very few patient deaths are related to the malfunction of a pacing device. Pacer patients are generally elderly (average age is approximately 70 years) and many experience a variety of medical problems in addition to their need for pacing support.

Physicians realize that all pacers, whether or not involved in a notification, are subject to failure at any time. Therefore, most monitor the devices routinely. If a patient dies, physicians normally consider pacer malfunction as a possible cause, and they notify the manufacturer as appropriate. Cordis investigates all such reports thoroughly. If the Company were instead to check every report of a patient death, its Customer Service personnel would constantly be involved in many unnecessary and unproductive investigations. Investagative efforts are better spent focusing on the reports indicating likely pacer anomalies or other possible product problems.

The appropriateness of this approach was underscored by a subsequent investigation of 45 reports of death among Gamma pacers patients. This study was carried out by the Company's Product Service Department and provided to the FDA. The findings indicated that none of the 45 deaths investigated was attributable to pacer malfunction.

3. Messrs. Casey and Spanioli testified that, in August 1983, Cordis management learned of an internal study of Gamma cells which had been initiated in October 1980 and discontinued in July 1982 without the results ever having been reported. The study involved the storage at various temperatures of 200 Gamma cells rejected from production for various reasons. By the end of the study, all units stored at 50°C had depleted within 21 months. Had this study been reported, the information might have been helpful in establishing the cause of the early Gamma battery depletions sooner than was the case.

Cordis reprimanded the power sources engineer who performed the study without reporting its results to his supervisors. Also, the Company has now issued a new corporate policy to assure that all technical data is reported promptly to at least two levels of supervision.

4. Messrs. Casey and Spanioli testified that they were informed by the Company that all copies of an internal audit which they requested had been destroyed. They then testified that, pushed further, the Company subsequently produced a copy.

The report in question concerned an internal investigation made in September 1983 to identify possible processing or component deviations that could be contributing to the early battery depletion of Gamma cells. Such audits are comprehensive and candid reviews and, as is standard industry practice, are designed solely for internal distribution. Further, once the conditions cited have been evaluated and/or corrected, Company policy provides that all copies of the report be destroyed.

Consequently, all official copies of the audit report were destroyed, or supposed to have been destroyed, some five weeks before the start of the FDA inspection in question. When the FDA Investigator requested a copy of the report, he was furnished copies of the destruction records. Subsequently, an unauthorized draft copy of the report, clearly marked as a draft, was located. Although this represented a failure by an employee to follow the Cordis procedures requiring destruction, the Company provided the FDA with the draft copy to comply as fully as possible with the Investigator's request.

In retrospect, Cordis concurs with the FDA Investigator's position that this report concerned an investigation of a field problem and should not have been treated as an internal audit. In the future, such investigations will be maintained as records pertaining to the devices being investigated and will be available for FDA review. The Company policy on internal audits has been changed to state that investigations of product complaints or product failure will not be classified as internal audits.

5. In response to a question, Mr. Casey testified that, early in the summer of 1984, the FDA discovered a wiring defect problem in certain models of the Company's Lambda and Stanicor Theta devices. In actual fact, Cordis issued its initial warning of potential "no output failures" by way of a Product Update in April 1982. Additional Updates have been issued every six months since. Copies of all six Updates were sent to the FDA as well as to some 15,000 monitoring physicians of record. Further, throughout this more than three year period, the FDA has inspected and corresponded with the Company concerning this potential problem. Thus, the problem was not "discovered" by the FDA, and certainly not in the summer of 1984.

The Company's position on this situation was that, given the low incidence of product failures and the fact that the cumulative survivals for these models met their original reliability predictions, the Updates which it issued served as a suitable means for notifying physicians of the potential failure mode. The situation, in Cordis' judgment, did not occur frequently enough to justify a formal notification or recall. Recently, Cordis complied with an FDA request that it issue a notification on these devices. Nevertheless, the Company remains steadfast in its belief that the need for this notification was questionable in light of the low-level incidence of failures among pacers in the group.

6. Mr. Casey correctly testified that, in September 1980, the Company initiated a process correction that eliminated the potential "no output" problem associated with certain Lambda/Theta pacers. It was also observed that 2200 of the earlier (uncorrected) units were subsequently distributed, the implication being that the Company might knowingly have marketed defective or potentially defective products. Again, that was not the case.

In September 1980, the Company issued a change order that required the filling of all unfilled plated-through holes on circuit boards. At the time the change was made, the Company had received just 10 verified plated-through hole failures among the 22,659 190A pacers implanted for up to 52 months. Because the incidence of these failures was low (just one of every 2266 units) and because no failures had occurred in any other pacer models at that time, Cordis determined that the potential defect would not occur frequently enough to warrant stopping shipment of or reworking pacers manufactured prior to the process change.

7. Testimony by Mr. Casey also revealed that the Company's legal files contained 57 complaints not contained in its master complaint file. I would simply like to emphasize for the record that, in response to the FDA's earlier observation, all complaints received by the Legal Department are now transcribed onto the appropriate Cordis form and sent to the Product Service Department for processing and filing in the master complaint file.

8. A concern raised by you, Mr. Chairman, related to the fact that some 7000 of the more than 30,000 Lambda and Theta pacers sold over the years are not registered with the Cordis Registry. While this number includes some 6000 units sold in foreign markets, as you observed, 783 of the pacers were distributed in the United States. For the record, it is important to emphasize that registration information is not easily obtained, despite the best efforts of Cordis or any other company. Studies have indicated that some 5% of pacers are never registered with the manufacturer. Unless incentives are developed to encourage hospitals or physicians to respond, such as the threat of withholding Medicare payment, the proposed National Registry data--which must be supplied through company records--will be equally flawed or incomplete.

Finally, it is my understanding that the Committee staff has requested from FDA copies of all FD 483's related to Cordis, including the Company's responses. I am concerned that presenting one without the other--i.e., including an observation without the corresponding Cordis reply--could be misleading and possibly damaging to the Company. Therefore, I respectfully request that the published Committee report, to the extent it cites specific FDA inspection observations, include in every instance and in direct conjunction the appropriate Company response.

I will not claim that my appearance before the Committee was an enjoyable experience. It was not, particularly under the circumstances. Hopefully, however, it was constructive for the Committee and for the interests of the Nation. I would welcome the opportunity to continue to assist you and the Committee in any way I can.

Sincerely,

Norman R. Weldon

Norman R. Weldon
President